EXHIBIT 1

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     IN RE:
                                    :SUPERIOR COURT OF
 2
     PELVIC MESH/GYNECARE
                                    :NEW JERSEY
    LITIGATION
                                    :LAW DIVISION -
 3
                                    :ATLANTIC COUNTY
                                    :MASTER CASE 6341-10
 4
                                    :CASE NO. 291 CT
 5
                                    :Civil Action
       CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF
 6
 7
                       CONFIDENTIALITY
 8
         EXPERT WITNESS TESTIMONY OF MILES MURPHY, M.D.
 9
10
                       November 30, 2012
11
12
                    Videotaped deposition of MILES MURPHY,
    M.D., held at BUTLER SNOW, 500 Office Center Drive,
13
14
     Suite 400, Blue Bell Conference Room, Fort Washington,
15
    Pennsylvania, commencing at approximately 9:43 a.m.,
16
    before Margaret M. Reihl, a Certified Realtime
17
    Reporter, Certified Court Reporter and Notary Public
18
     for the State of New Jersey and Commonwealth of
19
     Pennsylvania.
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                   GOLKOW TECHNOLOGIES, INC.
23
                877.370.3377 ph 917.591.5672 fax
                       deps@golkow.com
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3	BY: ADAM M. SLATER, ESQUIRE 103 Eisenhower Parkway	4	No. 420 Gynecare Prolift, Total Pelvic Floor Repair System	
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	Page 7			Page
1	CONFIDENTIAL DESIGNATION INDEX	1	THE VIDEOGRAPHER: We're now on the	
		2	record. My name is David Lane. I'm the videographer	
2	PAGE 163 LINE 2 THROUGH PAGE 163 LINE 20	3	for Golkow Technologies. Today's date is	
3	PAGE 164 LINE 2 THROUGH PAGE 165 LINE 20	4	November 30th, 2012. The time on the monitor is	
4	PAGE 211 LINE 22 THROUGH PAGE 212 LINE 1	5	9:43 a.m. This video deposition is taking place in	
5	PAGE 212 LINE 10 THROUGH PAGE 212 LINE 14	6	Fort Washington, Pennsylvania in regard to pelvic	
6	PAGE 243 LINE 18 THROUGH PAGE 244 LINE 15	7	mesh. The deponent today is Dr. Miles Murphy.	
7	PAGE 252 LINE 21 THROUGH PAGE 253 LINE 18	8	Counsel will be noted on the stenographic record.	
8	PAGE 254 LINE 4 TRHOUGH PAGE 254 LINE 24 PAGE 256 LINE 9 THROUGH PAGE 256 LINE 11	9	The court reporter today is Peg Reihl	
9		10	and will now swear in the witness.	
10	PAGE 272 LINE 10 THROUGH PAGE 272 LINE 19 PAGE 273 LINE 10 THROUGH PAGE 274 LINE 23	11	MILES MURPHY, M.D., having been	
11 12	PAGE 275 LINE 10 THROUGH PAGE 274 LINE 25 PAGE 275 LINE 19 THROUGH PAGE 276 LINE 13	12	duly sworn as a witness, was examined and	
13	PAGE 276 LINE 19 THROUGH PAGE 276 LINE 13	13	testified as follows	
14	PAGE 284 LINE 19 THROUGH PAGE 284 LINE 12	14	THE VIDEOGRAPHER: Please begin.	
15	PAGE 547 LINE 16 THROUGH PAGE 548 LINE 15	15	MR. SLATER: Did we place our	
16		16	appearances on the record yet?	
17		17	THE VIDEOGRAPHER: Stenographic.	
18		18	MR. SLATER: Oh, you did it. Okay,	
19		19	great.	
20		20	BY MR. SLATER:	
21		21	Q. Good morning, Dr. Murphy.	
22		22	A. Good morning.	
		23	Q. Just to introduce myself to you, I'm Adam	
23				
23 24		24	Slater. I'm here to take your deposition.	

		LLI	on and order or confidentiall	
	Page 10			Page 12
	right?	1	Here in Exhibit Murphy-1, the start of the	
2	A. Yes.	2	exhibit is your report, your first report in this	
3	Q. You understand you're under oath now and	3	case, correct?	
4	have to tell the truth in response to every single	4	A. I don't I guess I don't know exactly what	
5	question I ask you today?	5	you mean by my first.	
6	A. Yes.	6	Q. You've written two reports in this case that	
7	Q. If there's a question I ask you that you	7	I've seen.	
8	don't understand for any reason, please tell me that	8	Are you aware of having written more than	
9	and I'll reask the question, okay?	9	two reports?	
LO	A. Okay.	10	A. I just thought you might mean like a draft,	
11	Q. If there's something that's unclear, you	11	like I didn't write it all at once, I didn't sit down	
L2	maybe have to explain to me what it is that I'm not	12	and write it all at once.	
L 3	making clear to you, but, ultimately, you can explain	13	Q. No, and I'm actually not interested in your	
L 4	to me what's unclear, and we'll get to the bottom of	14	drafts, just like the defense wouldn't be interested	
L5	it and we'll get a responsive answer, okay?	15	in drafts written by plaintiff experts. Court rules	
.6	A. Okay.	16	say we're not supposed to ask about that. So I'll	
L7	Q. Otherwise, if you just answer the question,	17	start over.	
L8	we're going to assume you understood it and you were	18	Here in Exhibit Murphy-1, the first 30 pages	
19	doing your best to answer as truthfully and accurately	19	is the first report that you authored in this	
20	as you possibly could, okay?	20	litigation as an expert witness for Ethicon and	
21	A. Sounds good.	21	Johnson & Johnson, correct?	
22	Q. If counsel objects, he'll be objecting to	22	A. Correct.	
23	the form of the question. He won't be giving you any	23	Q. And on Page 31 it says that your	
24	signals of what to do. He won't be trying to signal	24		
	you whether or not to answer a question responsively.	25	That's what you're charging in this case?	
ری	you whether of not to answer a question responsivery.	23	That's what you're charging in this case.	
	Page 11			Page 13
1	That would be improper under the court rules in the	1	A. Yes.	
2	State of New Jersey, which governs this deposition.	2	Q. Then it says in the past four years you gave	
3	But he is allowed to object. Let him make his	3	expert testimony in only one case where the	
4	objection and then I cannot really imagine a situation	4	plaintiff's name was Neff, N-e-f-f, and the defendant	
5	where you wouldn't go ahead and answer the question,	5	was Collins, C-o-l-l-i-n-s, in Lycoming,	
6	okay.	6	L-y-c-o-m-i-n-g, County, Pennsylvania in 2009.	
7	A. Okay.	7	A. That was to the best of my recollection,	
8	MR. SLATER: You have stickers there,	8	yes.	
9	please. Thanks a lot.	9	Q. When you say that you gave expert testimony	
L0	(Document marked for identification	10	in that case, you mean you actually testified in	
11	as Murphy Deposition Exhibit No. 1.)	11	court?	
L2	BY MR. SLATER:	12	A. Correct.	
13	Q. I'm going to hand you an exhibit that we've	13	Q. Have you acted as an expert in any other	
L 4	marked as Murphy-1.	14	matters besides the Neff case?	
L5	Is that the first report you wrote in this	15	A. Yes.	
	case?	16	Q. In your career?	
L 7	A. Yes.	17	A. Yes.	
L 7	Q. Does it have attached to it your Curriculum	18	Q. Okay. How many times?	
	Vitae?	19	A. I believe three other times, and I testified	
20	A. Yes.	20	once in New Jersey early in my career. I testified	
			once in Allentown, Pennsylvania. Those are the only	
21	Q. Now, it has attached to it well,	21	·	
22	actually, let me start over.	22	times I recall testifying in court.	
. ~				
	The report itself is 30 pages long, correct?	23	Q. What were the other well, let's start	
23 24 25	A. I have to look at it. Q. I'm going to rephrase the question.		with Neff. What was the subject matter of the Neff	

_	Confidencial - Subject to Scipula			
	Page 14		O. Danishama and J. C. P. of a disconnection	Page 16
	case?	1	Q. Do you have an understanding that when	
2	A. If I recall, it was an injured ureter in a	2	physicians treat patients, they make decisions and	
	hysterectomy case.	3	exercise their medical judgement in deciding what to	
4	Q. Medical malpractice case?	4	recommend to a patient, how to treat the patient,	
5	A. Correct.	5	those types of things?	
6	Q. Who were you the expert for?	6	A. Yes.	
7	A. The defendant.	7	Q. Do you have an understanding that when a	
8	Q. In the other cases you've been an expert in,	8	surgeon performs an operation, for example, a Prolift®	
9	have they been medical malpractice cases?	9	procedure, that the surgeon during the procedure will	
10	A. Yes.	10	be exercising his or her medical or surgical judgement	
11	Q. Were you the expert for the defendant in	11	in making decisions on how to perform the procedure	
12	each of those cases?	12	during the actual operation?	
13	A. Yes.	13	A. That sounds reasonable as a definition.	
14	Q. Have you ever been the expert for a	14	Q. It's certainly something that the physicians	
15	plaintiff in any litigated matter?	15	that you're familiar with do, right?	
16	A. No.	16	A. Correct.	
17	Q. Have you ever been asked to look at a matter	17	Q. Something you do when you perform	
18	on behalf of a plaintiff, to review it, to see if you	18	procedures, correct?	
19	could act as an expert?	19	A. Correct.	
20	A. Maybe once. I don't recall for sure.	20	Q. Something you did when you performed	
21	Q. The one that you're saying maybe once, was		Prolift® procedures, correct?	
22	there a matter you looked at and said you couldn't act	22	A. Correct.	
23	as the expert for some reason?	23	Q. And, essentially, you have the Prolift®	
24	A. Yeah, I certainly didn't say yes, I could	24	procedure, which is a template, and then you have to	
25	act as the expert because I think I would have then	25	exercise your judgement in evaluating the particular	
	Page 15			D 45
	1 age 13			Page 17
1	proceeded.	1	patient and how you're going to actually, for example,	Page 17
1 2		1 2	patient and how you're going to actually, for example, trim the mesh and implant the mesh, correct?	Page 17
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	Page			Page 20
	of the opinion, most of the body of the report is	1	disclose what you relied on in forming your opinions;	
2	based on scientific data, published data and whenever	2	did you understand that when you authored this report?	
	I used, for instance, a paper that had been published,	3	A. I think so. I'm not a lawyer but	
4	I referenced that in the report.	4	Q. When you wrote this report and you attached	
5	Q. So whatever clinical data you relied on in	5	this bibliography to it	
6	writing your report is found in the bibliography?	6	A. Yes.	
7	A. No.	7	Q did you intend to give notice to myself	
8	Q. Well, besides what's referenced in the	8	and other people in this case as to what published or	
9	bibliography, what other clinical data did you rely on	9	documented clinical data you were relying on in	
10	in forming your opinions in this case?	10	forming your opinions in the report?	
11	A. My own medical experience, my own clinical	11	MR. SNELL: Objection, go ahead.	
12	experience and that of my colleagues.	12	THE WITNESS: When I wrote the report	
13	Q. To the extent that clinical or medical data	13	and compiled the bibliography, I wanted to make sure	
14	is published someplace and you relied on it to some	14	that if there was important literature that I wanted	
15	extent in forming your opinions, is it listed in the	15	to reference in my report that I included in the	
16	bibliography?	16	bibliography. That was my main purpose of doing the	
17	A. For this first report, yes.	17	bibliography.	
18	Q. At the time you wrote and signed your first	18	BY MR. SLATER:	
19	report, which is Murphy-1, the published or documented	19	Q. So at the time that you wrote the report,	
20	clinical data that you were relying on was listed in	20	any literature that was rephrase.	
	the bibliography from Page 32 to 38, correct?	21	So at the time you wrote this report and	
21	MR. SNELL: Objection, form.		signed it, any published data, clinical data that you	
22	·	22	• • • • • • • • • • • • • • • • • • • •	
23	THE WITNESS: That was a pretty long	23	felt was important to you in forming your opinions,	
24	question, but I think the answer is yes.	24	you listed in the bibliography?	
25	BY MR. SLATER:	25	MR. SNELL: Objection, form.	
	Page	19		Page 21
1	Q. Okay. Well, what I was saying is at the	1	THE WITNESS: Not necessarily. I	
1 2	Q. Okay. Well, what I was saying is at the time you formed your opinions that are set forth in	1 2	THE WITNESS: Not necessarily. I simply	
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2	time you formed your opinions that are set forth in	2	simply	
2	time you formed your opinions that are set forth in Murphy-1, the first report you authored, to the extent	3	simply BY MR. SLATER:	
2 3 4 5	time you formed your opinions that are set forth in Murphy-1, the first report you authored, to the extent that you relied on data that is actually published,	2 3 4	simply BY MR. SLATER: Q. Well, tell me.	
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	Confidential - Subject to Scipula	LLI	on and order or confridentiall	
	Page 22			Page 24
1	on this list of additional materials before you signed	1	Q. Didn't see any of those videos, correct?	
2	•	2	A. Correct.	
3	A. Briefly, yes.	3	Q. Have you seen the video of anyone's	
4	Q. When you say "briefly," what do you mean?	4	deposition that's ever been taken in this case?	
5	A. I looked at them.	5	A. No.	
6	Q. Well, when you say "looked at them," for	6	Q. Did you ever ask to see any of the videos of	
7	example, there could be a deposition transcript, and	7	the actual deposition testimony of any witness in this	
8	I'll take an example from this additional list of	8	case?	
9	materials. There's the deposition transcript of	9	A. No.	
.0	exhibits of Piet Hinoul, P-i-e-t H-i-n-o-u-l, listed.	10	Q. In writing the report, which we marked as	
1	Did you read that entire transcript and	11	Murphy-1 well, rephrase.	
2	exhibits?	12	This list of additional materials, are these	
.3	A. No, I did not. That's a very long	13	basically other materials that you wanted to list in	
4	there's a couple volumes of that, but I had certainly	14	case you wanted to mention them during trial so you	
.5	reviewed it.	15	could say, hey, you know that I listed them; is that	
6	Q. Well, when you say you reviewed it, what	16	basically the purpose?	
.7	does that mean?	17	MR. SNELL: Object to form. Go ahead.	
.8	A. I read some of it.	18	THE WITNESS: I think that's a fair	
.9	Q. How many pages of it did you read?	19	assessment because from the time I drafted my report,	
20	A. I don't recall.	20	there were a lot of depositions and your you know,	
21	Q. Did you read more than ten pages of that	21	the plaintiffs' expert had referenced things, and I	
22	deposition?	22	wanted to make sure that I could reference other	
23	A. Yes.	23	things as well.	
24	Q. But you can't tell me beyond that what you	24	BY MR. SLATER:	
25		25	Q. Okay. Is it fair to say that at the time	
	Page 23			Page 2
1	A. I can remember some of the things that I	1	you wrote your first report, which is Murphy-1, you	
2	read in it.	2	had not read all of the materials listed on the	
3	Q. Well, was there well, we'll come back to	3	list additional list of materials?	
4	that.	4	A. Yes.	
5	Did you read it says rephrase it.	5	Q. Is it fair to say you did not rely on all	
6	It says Jessica Shen, deposition transcript	6	the materials listed in the additional list of	
7	with exhibits.	7	materials when you actually formed your opinions?	
8	Did you read the entire deposition and	8	A. I would say that I didn't rely on all of	
9	exhibits?	9	them, but it's very likely that I would have read some	
.0	A. No.	10	of the other additional materials, just not quoted	
.1	Q. It says Judi Gauld, deposition transcript	11	them in my bibliography.	
.2	with exhibits.	12	Q. When you wrote your report, you set forth	
.3	Did you read the entire deposition and	13	opinions, and I'm talking about your first report,	
.4	exhibits?	14	Murphy-1, you set forth certain opinions in the	
.5	A. I did not.	15	report, correct?	
.6	Q. It says David Robinson, deposition	16	A. Correct.	
.7	transcript with exhibits.	17	Q. Were those all of the opinions you had	
.8	Did you read the entire deposition and read	18	formed with regard to this litigation at the time that	
.9	all the exhibits?	19	you authored that report?	
20	A. No.	20	A. I don't know that I I mean, I have lots	
21	Q. And with regard to Jessica Shen, Piet	21	of opinions about this case. I don't know that every	
2	Hinoul, Judi Gauld and David Robinson's deposition	22	single solitary one was listed in the report.	
3	transcripts that are listed here, did you actually	23	Q. You understood that one of the purposes of	
24	watch the videos of their depositions?	24	your report was to give notice to attorneys in the	
25	A. No.	25	litigation like myself of what your opinions were,	
د،	11. 110.	25	nugation like myself of what your opinions were,	

	Page	26		Page 28
	correct?	1	1 1	
2	A. Correct.	2	were those things you listed because you planned to	
3	Q. Okay. Did you endeavor, when you wrote this	3	read them at a later date?	
4	report, to list each of the opinions that you had	4	A. I'm sorry. Which are you referring to? Are	
5	formed at the time that you authored the report; was	5	you referring to something in the bibliography?	
6	that your goal?	6	Q. I'm looking the list of additional	
7	A. My goal was simply to write a report that	7	materials.	
8	reflected my views of Prolift® in this case.	8	A. Oh, additional materials. I'm sorry. Can	
9	Q. Okay. And the opinions set forth in your	9	you repeat the question then?	
10	first report, Murphy-1, accomplished that, from your	10	Q. Sure. Go to the page where you listed the	
11	perspective?	11	four deposition transcripts?	
12	A. I think so, but I think that in looking at	12	A. Yes.	
13	other people's depositions, there may have been things	13	Q. Because right below that are a list of	
14	that they covered that I didn't think were necessarily	14	• •	
15	essential to cover in my first report and, therefore,	15	A. Yes.	
16	wanted to have some supplemental material later on.	16	Q. Might as well turn to it.	
17	Q. At the time that you authored your first	17	A. Yeah.	
18	report	18	Q. Right before your CV.	
19	A. Yes.	19	Are you with me now?	
20	Q the day that you put your signature, your	20	A. Yes.	
21	electronic signature on there, typed your name in, did	21	Q. On the last page of the list of additional	
22	that represent the opinions you had formed as of that	22	materials, there's a list of expert reports under	
23	point in time with regard to this litigation?	23	three headings, expert general reports, Plaintiff	
24	MR. SNELL: Objection, form.	24	Gross, Plaintiff Wicker.	
25	THE WITNESS: Yes.	25	Do you see that?	
	Page	27		Page 29
1	BY MR. SLATER:	1	A. Yes.	
2	Q. In the report you listed many facts from	2	Q. At the time that you authored Murphy-1, your	
3	various sources of information that you referred to in	3		
4		-	first report, had you read those, or did you simply	
	the report, correct?	4	list those in the list of additional materials because	
5	the report, correct? A. Yes.			
5	Ī.	4	list those in the list of additional materials because	
	A. Yes.	4 5	list those in the list of additional materials because they were things that you intended to read later?	
6	A. Yes.Q. Did you, in writing the report, attempt to	4 5 6	list those in the list of additional materials because they were things that you intended to read later? A. The Anne Weber expert report, I believe I	
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6 7 8	A. Yes. Q. Did you, in writing the report, attempt to list those facts that you felt were most important to you in forming your opinions as set forth in the	4 5 6 7 8	list those in the list of additional materials because they were things that you intended to read later? A. The Anne Weber expert report, I believe I had that at the time I drafted Murphy-1. I certainly did not read every page of that report, but I had read	
6 7 8 9	A. Yes. Q. Did you, in writing the report, attempt to list those facts that you felt were most important to you in forming your opinions as set forth in the report?	4 5 6 7 8 9	list those in the list of additional materials because they were things that you intended to read later? A. The Anne Weber expert report, I believe I had that at the time I drafted Murphy-1. I certainly did not read every page of that report, but I had read a significant amount of it. I don't think that I had	
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	Page 30			Page 32
1	correct?	1	this several times now, one of the things that you	
2	A. I'm sorry. Could you repeat the question.	2	want to do if you're being well, let me rephrase.	
3	Q. Sure. To the extent that you found that a	3	Let me ask you, what do you think your role	
4	study or a document was important enough to you that	4	is as an expert witness in this litigation?	
5	you actually wanted to reference it in the report as	5	A. My role is to tell the truth about my	
6	having been relied on in forming the opinions, those	6	opinions.	
7	things are listed in the bibliography, correct?	7	Q. One of the things that you're intending to	
8	A. Yeah, I think that's fair to say. Those are	8	do is to offer opinions ultimately in a courtroom to a	
9	the things that I thought were important when I was	9	jury that's going to decide certain issues in this	
10	drafting the report, and I thought they were important	10	case, correct?	
11	to reference.	11	A. Correct.	
12	Q. Are you aware of how many documents have	12	Q. And one of the things that you want to do	
13	been produced, the volume of documents that have been	13	when you give those opinions is to have all of the	
14	produced in this litigation by Ethicon and Johnson &	14	necessary background information so that when you give	
15	Johnson to the plaintiffs? Do you have any idea of	15	those opinions, you can feel confident that they're	
16	that volume?	16	supported by the actual facts, right?	
17	A. I do not.	17	A. Sure.	
18	Q. And nobody has ever told you that?	18	Q. And with regard to the actual conduct of	
19	A. No.	19	Ethicon in terms of what the company was actually	
20	Q. Did you ever ask anybody how many documents	20	doing day-to-day, you didn't work at Ethicon, right?	
21	have you produced?	21	A. Correct.	
22	A. No.	22	Q. So the only knowledge you would have from	
23	Q. Have you ever tried to gain an understanding	23	that would be your personal interaction with people at	
24	of what types of documents have been produced? Did	24	Ethicon over the years; that would be one source of	
25	you ever want to say did you ever ask anyone, hey,	25	that information, correct?	
	Page 31			Page 33
1	Page 31 I want to know what you've produced so I can tell you	1	A. Correct.	Page 33
	I want to know what you've produced so I can tell you	1 2	A. Correct. O. And the other source of that information	Page 33
2	I want to know what you've produced so I can tell you what I need to see?	2	Q. And the other source of that information	Page 33
2 3	I want to know what you've produced so I can tell you what I need to see? A. I can tell you right now, I did not ask	2 3	Q. And the other source of that information would be whatever documents Ethicon provided you to	Page 33
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_	Confidential - Subject to Stipula	_		D 26
	Page 34			Page 36
	boy, I didn't realize that would be part of a record.	1	Q. It's the last thing that's listed here in	
2	That's something that I would want to know about.	2	your report on Murphy-1, correct?	
3	BY MR. SLATER:	3	A. Correct.	
4	Q. Well, to the extent that document were	4	Q. It's the last attachment to your report,	
	rephrase.	5	correct?	
6	The documents that Ethicon provided to you,	6	A. Correct.	
7	meaning the internal Ethicon documents, are listed in	7	Q. Is that your up-to-date CV?	
8	this list of additional materials, correct?	8	A. There may be some additions since then.	
9	A. Correct.	9	Something was just published this month.	
10	Q. The documents provided by Ethicon to you so	10	Q. What was just published this month?	
11	that you could form your opinions based on a full	11	A. I don't think it would have much bearing	
12	factual record did not include any e-mails, correct?	12	upon this case.	
13	I don't see any e-mails listed on this list of	13	Q. Not relevant to this case?	
14	additional materials, so am I correct?	14	A. Well, actually, it was a little bit	
15	MR. SNELL: Object to the form,	15	relevant. It had to do with risk factors for mesh	
16	actually misrepresents.	16	erosion in vaginal surgery and abdominal surgery, so I	
17	BY MR. SLATER:	17	guess it has some relevance.	
18	Q. Well, I'll ask you very simply.	18	Q. Where was that published?	
19	A. I'm sorry. Go ahead.	19	A. It was published in the what we call the	
20	Q. If you understand the question, you can	20	gold journal, Female Pelvic Medicine and	
21	answer it.	21	Reconstructive Surgery.	
22	A. I think what you're well, now I'm a	22	Q. And in that article you attempted to do	
23	little bit confused	23	what?	
24	Q. Let me ask	24	A. I was a co-author. It was what's called a	
25	A but I think some e-mails were referred to	25	Fellow's Pelvic Research Network. I was a mentor for	
	Page 35			Page 37
1	in other depositions that I've read.	1	that, and it was a case control study of what risk	
1 2	in other depositions that I've read. Q. This is what I want to ask you: In the list	1 2	that, and it was a case control study of what risk factors there are for mesh erosion when you place mesh	
	•		•	
2	Q. This is what I want to ask you: In the list	2	factors there are for mesh erosion when you place mesh	
2	Q. This is what I want to ask you: In the list of additional materials	2 3	factors there are for mesh erosion when you place mesh vaginally and when you place it abdominally.	
2 3 4	Q. This is what I want to ask you: In the list of additional materials A. Sure.	3 4	factors there are for mesh erosion when you place mesh vaginally and when you place it abdominally. Q. Are there different risk factors when it's	
2 3 4 5	Q. This is what I want to ask you: In the list of additional materials A. Sure. Q the actual Ethicon internal documents	2 3 4 5	factors there are for mesh erosion when you place mesh vaginally and when you place it abdominally. Q. Are there different risk factors when it's placed vaginally versus abdominally?	
2 3 4 5 6	Q. This is what I want to ask you: In the list of additional materials A. Sure. Q the actual Ethicon internal documents that Ethicon provided you, not things that were	2 3 4 5 6	factors there are for mesh erosion when you place mesh vaginally and when you place it abdominally. Q. Are there different risk factors when it's placed vaginally versus abdominally? A. That was the question we were trying to	
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	Confidential - Subject to Stipula	ill	on and order of Confidentiali	
-1	Page 38 evaluation seemed to suggest some other things, but I	,	consenting	Page 40
	think in the final manuscript, hysterectomy was the	1	consenting. MR. SLATER: Move to strike from	
3	only risk factor, and I believe it was listed for both	3	there's a lot to cover.	
4	vaginal and abdominal.	4	BY MR. SLATER:	
5	Q. Were there any other risk factors for	5	Q. Your Board certification, did you pass both	
6	vaginal erosion either place where the mesh is	6	the oral and written portions on the first try?	
7	either placed vaginally or abdominally, other than	7	A. I did.	
8	hysterectomy?	8	Q. Abington Memorial Hospital, how many beds	
9	A. I don't think that we came up with any other	9	are in that hospital?	
10	ones.	10	A. I could give you a	
11	Q. In your experience, are there any others	11	Q. Give me an estimate.	
12	that you're familiar with?	12	A a very rough estimation, 4 to 600.	
13	A. Yes. Certainly a history of smoking seems	13	Q. Where is that hospital located? It says	
14	to predispose patients to that, and that has been	14	Abington, Pennsylvania.	
15	shown in other studies. Certainly, theoretical risk	15	A. Yes.	
16	factors, things like diabetes, things that would lead	16	Q. How many gynecologists are in the department	
17	to poor wound healing, prior radiation, steroid use.	17	of obstetrics and gynecology currently?	
18	That's what I'm recalling at this time.	18	A. Again, it would be an estimation, 30 to 50.	
19	Q. When you refer to theoretical risks	19	Q. How much of your time do you spend on	
20	rephrase. When you refer to theoretical rephrase.	20	administrative work in connection with your role as	
21	When you refer to factors that could	21	chief of the section of urogynecology?	
22	theoretically increase the risk for an erosion, you	22	A. Probably in the range of 10 to 15 hours a	
23	mean these haven't been studied to the point where		month.	
24	that's been established?	24	Q. How many urogynecologists are in the	
25	A. It's a combination of, yes, that's partly it	25	department of obstetrics and gynecology?	
	Page 39			Page 41
1	and partly just I don't recall exactly. You know,	1	A. We just got our second.	
2	some studies were looking at abdominal mesh; some	2	Q. So when you say you just got your second,	
3	studies were looking at vaginal, and I know at some	3	when was that?	
4	point smoking was definitely noted as a risk, but I'm	4	A. Within the year.	
	not sure whether that was an abdominal or a vaginal	5	Q. So before that you were the only	
6	mesh placement. O. As you sit here now, is there a study you're	6	urogynecologist in that department?	
7	familiar with that actually established that smoking	7	A. I was the only urogynecologist. There were two what we call female urologists. There's an	
8	•	8	· ·	
9	is a risk factor one way or the other with regard to	9	overlap in this field between the field of urology and	
10	erosion?	10	gynecology.	
11	A. I could not quote the study.	11	Q. Was there a section of urology that those	
12	Q. In your consenting of patients with regard	12	female urologists would technically fall within? A. I believe all the urologists fall under the	
13	to the Prolift® from the very beginning, did you tell patients who were smokers that that was a risk factor	13	· ·	
14	•	14	division or excuse me the department of surgery,	
15	for them to have a higher risk for erosion?	15	and so they would have fallen under the division of	
16	A. I wouldn't say that I necessarily would counsel every patient who was a smoker of that, but I	16	urology in the department of surgery. Q. So as chief of the section of urogynecology,	
17	* *	17	•	
18	certainly could remember cases where I would say when I talk about the risk of erosion with every patient. I	18	until very recently that section was made up of one	
19	I talk about the risk of erosion with every patient, I	19	urogynecologist, yourself, correct?	
20	would say, oh, you know, in your case, since you're a	20	A. Let me I just recalled something. My	
21	smoker, that risk is probably higher. Q. So for some smokers you told them, for some	21	partner Dr. Lucente was also on the in the division	
22			as well.	
			O He was in the division Did he also	
22 23 24	you didn't; it just depended basically if you thought	23	Q. He was in the division. Did he also	
			Q. He was in the division. Did he also typically use Abington Memorial Hospital for the treatment of his patients?	

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		ge 42		Page 44
1	A. He did probably from 2004 excuse me		Gynecology considered to be a high level medical	
2	from 2000 maybe '02 to 2004 or '05, around that time.		? journal?	
3	He phased out of operating much there and pretty much	3		
4	operated up in Allentown.	4		
5	Q. During the time you've been chief of the	5	· · ·	
6	section of urogynecology, that section has essentially	6	* * * * * * * * * * * * * * * * * * * *	
7	been you, right?	7		
8	A. Since I've been the chief, correct.	8		
9	Q. So you were chief of a section of	9	·	
10	urogynecology where you were the one urogynecologist?	10	THE WITNESS: I don't think I'd ever	
11	A. Correct.	11	mention that, but, no, they wouldn't be particularly	
12	Q. It says that you've been a journal peer	12	e impressed.	
13	reviewer for four different journals.	13	BY MR. SLATER:	
14	Do you see that?	14	Q. The International Urogynecology Journal, is	
15	A. Yes. Well, I don't see it yet, but I can	15	that considered to be a high quality journal?	
16	find it.	16	A. Yes.	
17	Q. Page 5 of your CV.	17	Q. How about the American Journal of Obstetrics	
18	A. Yes.	18	& Gynecology?	
19	Q. In your role as a peer reviewer for the	19	A. Yes.	
20	American Journal of Obstetrics & Gynecology, what have	20	Q. How long have you been a reviewer for	
21	you actually done?	21	International Urogynecology Journal?	
22	A. The journal has sent me papers, they've	22	A. I would guess at least eight years.	
23	asked me to review them and give my opinions regarding	23	Q. How about the American Journal of Obstetrics	
24	the value and quality of the study.	24	& Gynecology, how long?	
25	Q. How many times?	25	A. Same.	
	Pag	ge 43		Page 4
		,		
1	A. For the American Journal?	1	O. You started reviewing basically right out of	
1		1		
2	Q. Yeah.	2	your fellowship?	
2	Q. Yeah.A. I would guess somewhere in the range of 10	3	your fellowship? A. Correct.	
2 3 4	Q. Yeah.A. I would guess somewhere in the range of 10 to 15.	3	your fellowship? A. Correct. Q. Your fellowship was under Dr. Lucente at his	
2 3 4 5	Q. Yeah.A. I would guess somewhere in the range of 10 to 15.Q. The International Urogynecology Journal,	2 3 4 5	 your fellowship? A. Correct. Q. Your fellowship was under Dr. Lucente at his practice, correct? 	
2 3 4 5 6	Q. Yeah.A. I would guess somewhere in the range of 10 to 15.Q. The International Urogynecology Journal, same type of work?	2 3 4 5	your fellowship? A. Correct. Q. Your fellowship was under Dr. Lucente at his practice, correct? A. No.	
2 3 4 5 6 7	 Q. Yeah. A. I would guess somewhere in the range of 10 to 15. Q. The International Urogynecology Journal, same type of work? A. Yes. 	2 3 4 5	 your fellowship? A. Correct. Q. Your fellowship was under Dr. Lucente at his practice, correct? A. No. Q. Oh, I actually mixed you up with somebody 	
2 3 4 5 6 7 8	 Q. Yeah. A. I would guess somewhere in the range of 10 to 15. Q. The International Urogynecology Journal, same type of work? A. Yes. Q. How many times have they sent you articles 	2 3 4 5 6	your fellowship? A. Correct. Q. Your fellowship was under Dr. Lucente at his practice, correct? A. No. Q. Oh, I actually mixed you up with somebody else.	
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2 3 4 5 6 7 8 9	 Q. Yeah. A. I would guess somewhere in the range of 10 to 15. Q. The International Urogynecology Journal, same type of work? A. Yes. Q. How many times have they sent you articles to look at? A. Twenty to 30. 	2 3 4 5 6 7 8 9	2 your fellowship? 3 A. Correct. 4 Q. Your fellowship was under Dr. Lucente at his practice, correct? 5 A. No. 6 Q. Oh, I actually mixed you up with somebody gelse. 6 A. It's okay. 7 Q. Where did you do your fellowship?	
2 3 4 5 6 7 8 9 10	 Q. Yeah. A. I would guess somewhere in the range of 10 to 15. Q. The International Urogynecology Journal, same type of work? A. Yes. Q. How many times have they sent you articles to look at? A. Twenty to 30. Q. European Journal of Obstetrics & Gynecology, 	2 3 4 5 6 7 8 9	your fellowship? A. Correct. Q. Your fellowship was under Dr. Lucente at his practice, correct? A. No. Q. Oh, I actually mixed you up with somebody else. A. It's okay. Q. Where did you do your fellowship? A. The University of Louisville.	
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	Page 46			Page 48
1	A. Correct.	1	MR. SNELL: Objection, form.	
2	Q. Those standards are relied on by those who	2		
3	are reading the articles in journals like that to give	3	Q. It's a reasonable question, right?	
4	them the comfort that they can believe what they're	4	A. Yes. I think that it certainly might make	
5	reading and trust the information they're being	5	you question other things, not necessarily everything,	
6	provided, correct?	6	but, yes.	
7	A. Correct.	7	Q. One of the things that the high level	
8	MR. SNELL: Objection, form. Go ahead.	8	journals require is disclosures of potential bias and	
9	THE WITNESS: Correct.	9	potential sources of conflict of interest, correct?	
10	BY MR. SLATER:	10	A. Correct.	
11	Q. The reason that journals are considered high	11	Q. Why is that disclosed?	
12	level journals, those that have attained that status,	12	A. So that everybody knows where everybody is	
13	is a product of what is perceived in the medical	13	coming from.	
	community to be the strict peer-review process,	14	Q. Why is that important?	
14	correct?		A. Because bias exists in everything we do in	
15	A. It's part of it.	15	life and certainly in medical research, and you want	
16	•	16	·	
17	Q. If it were to turn out that somebody who published an article in a medical journal falsified	17	to know someone's biases when you're reading their work so that you have that knowledge.	
18	· ·	18	•	
19	data, would that be a very egregious situation? MR. SNELL: Objection, form.	19	Q. If it were to turn out that someone were to	
20	•	20	write an article that was published in a high level	
21	THE WITNESS: If they falsified data,	21	journal and the person misrepresented potential	
22	that would be I'm not so familiar with the term	22	conflict of interest or bias that had gone into the	
23	egregious, but, yeah, that would be bad.	23	study or the article being reported, would that be	
24	BY MR. SLATER:	24	significant?	
25	Q. Well, let me ask you in your own words, if	25	MR. SNELL: Objection, form.	
	Page 47			Page 49
1	Page 47 it were to turn out that there was somebody who wrote	1	THE WITNESS: It depends on the intent.	Page 49
1 2		1 2		Page 49
	it were to turn out that there was somebody who wrote		•	Page 49
2 3	it were to turn out that there was somebody who wrote an article that turned out to have falsified data with	2	If they simply forgot to mention something that was	Page 49
3 4	it were to turn out that there was somebody who wrote an article that turned out to have falsified data with regard to the results of whatever was being studied,	2 3	If they simply forgot to mention something that was other people might consider very significant, then I	Page 49
3 4	it were to turn out that there was somebody who wrote an article that turned out to have falsified data with regard to the results of whatever was being studied, from your perspective, what would be the significance	2 3 4	If they simply forgot to mention something that was other people might consider very significant, then I don't think that that's that big a deal, but,	Page 49
2 3 4 5	it were to turn out that there was somebody who wrote an article that turned out to have falsified data with regard to the results of whatever was being studied, from your perspective, what would be the significance of that?	2 3 4 5	If they simply forgot to mention something that was other people might consider very significant, then I don't think that that's that big a deal, but, certainly, if someone falsified data, that would be a	Page 49
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	Post 50			
	Page 50		1 1 10	Page 52
1	Q. If the author of a study were to	1		
2	affirmatively state, for example, that the	2	BY MR. SLATER:	
3	manufacturer of the device being studied had no input	3	Q. In a high level medical journal, any	
4	into the design of the study, but it turned out that	4	affirmative misrepresentation about the involvement of	
5	the manufacturer actually did have input into the	5	the manufacturer of a device that was being studied in	
6	design of the study, that would be significant, right?	6	the article would be significant; any	
7	MR. SNELL: Objection, form.	7	misrepresentation would be significant, right?	
8	THE WITNESS: Yes, I think if it was a	8	MR. SNELL: Objection, form.	
9	substantial input into the design of the study from	9	THE WITNESS: I think I just answered	
10	the company and there was no disclosure of that, that	10	that, and that it depends on how much involvement and	
11	would be significant.	11	what degree of significance we're talking about.	
12	BY MR. SLATER:	12	BY MR. SLATER:	
13	Q. If the author of a study published in a high	13	Q. So from your perspective as a peer reviewer,	
14	level journal were to affirmatively say that the	14	is it your testimony that your standards are, well, if	
15	manufacturer of the device being studied had no input	15	somebody misrepresents a little thing, it's okay.	
16	into the study design, then people reading that	16	They'd have to misrepresent something big for it to	
17	article would assume that that's a truthful statement	17	really matter; is that what you're telling this jury?	
18	that there was no input; fair statement?	18	A. My testimony what I'm telling the jury is	
19	MR. SNELL: Objection, form.	19	that it all depends on what we're talking about.	
20	THE WITNESS: Yes.	20	Q. Okay. If the author of an article published	
21	BY MR. SLATER:	21	about a medical device in a high level journal	
22	Q. If the author of a article published in a	22	represented there was no involvement in the writing of	
23	high level medical journal were to affirmatively	23	the manuscript by the manufacturer, and, in fact, the	
24	represent that the manufacturer of the device being	24	manufacturer's employees, several of them, went	
25	studied had no input or no involvement in the writing	25	through multiple drafts of the manuscript and made	
	Page 51			Page 53
1	Page 51 of the manuscript, people reading that would assume	1	substantive recommendations and asked for changes to	Page 53
1 2	of the manuscript, people reading that would assume	1 2	· · · · · · · · · · · · · · · · · · ·	Page 53
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-	Page 54			Page 56
	can ask him whatever I want.		would want to err on the side of most things being	
2	BY MR. SLATER:	2	substantive because you don't want people	
3	Q. Answer the question.	3	misrepresenting anything in an article, right?	
4	A. I would say concerned	4	MR. SNELL: Objection, form.	
5	MR. SNELL: I'm going to note my	5	THE WITNESS: I would simply view what	
6	objection to form. Go ahead.	6	I thought as substantive as substantive. I don't know	
7	BY MR. SLATER:	7	whether I'd be conservative or liberal in regard to	
8	Q. You would agree with me that if an author	8	that.	
9	affirmatively misrepresented in an article that the	9	BY MR. SLATER:	
10	manufacturer of the medical device being studied had	10	Q. If an author were to have made such a	
11	no involvement in the writing of the manuscript, and,	11	misrepresentation, one that you felt was substantive,	
12	in fact, the manufacturer's employees had substantive	12	that's an author who you would deem to not be	
13	material involvement in the content that actually was	13	trustworthy in terms of reporting information in a	
14	published, and due to their input certain things were	14	published article, right?	
15	changed in the article that were substantive, that	15	MR. SNELL: Objection, form.	
16	would be a very serious infraction by that author;	16	THE WITNESS: Yes.	
17	wouldn't it be?	17	BY MR. SLATER:	
18	MR. SNELL: Objection, form.	18	Q. And the article itself, if that were to come	
19	THE WITNESS: That would be something	19	out, that would be an article that you would say	
20	that I would be want to be aware of.	20	should be disregarded at that point, correct?	
21	BY MR. SLATER:	21	MR. SNELL: Objection, form. Go ahead.	
22	Q. It would be a very serious infraction of the	22	THE WITNESS: If I felt it was	
23	rules; wouldn't it be?	23	substantive enough that it misrepresented the reality	
24	MR. SNELL: Same objection to form.	24	of the outcomes of the study, then, yes.	
25	THE WITNESS: It depends on what		BY MR. SLATER:	
23	THE WITNESS. It depends on what	25	DI MIK. SEATEK.	
	Page 55			Page 57
1	when you say "substantive," I don't know what that	1	Q. If the author allowed rephrase.	
2	means.	2	If the input was substantive and changed the	
3	BY MR. SLATER:	3	content of what was actually concluded and what was	
4	O Whotavar von would define as substantive if			
_	Q. Whatever you would define as substantive, if	4	described in the article and it came to and it came	
5	that were to have happened, that would be a serious	4 5	out that this input had actually occurred and you felt	
5 6	- ·			
	that were to have happened, that would be a serious		out that this input had actually occurred and you felt	
6	that were to have happened, that would be a serious infraction?	6	out that this input had actually occurred and you felt it was substantive, strictly following the peer-review	
6 7	that were to have happened, that would be a serious infraction? MR. SNELL: Objection to form. Go	6	out that this input had actually occurred and you felt it was substantive, strictly following the peer-review process and rules, that article should be retracted	
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	Page		Page 60
	focusing on, though, right?		•
2	MR. SNELL: Objection, form.	2	
3	BY MR. SLATER:	3	
4	Q. Because people don't have time to read the	4	7 1 1
5	complete articles and all of the data and draw their	5	1 , 1 ,
6	own conclusions, generally rely on the conclusions by	6	Ī
7	the authors, right?	7	
8	MR. SNELL: Objection, form.	8	
9	THE WITNESS: I would disagree with	9	
10	that. Generally, when I look at an article, the first	10	• •
11	thing I do is I read the abstract. The first thing I	11	
12	do is sort of say what was the purpose, and then I go	12	
13	to the results section, and I read the results. Then	13	
14	I'm curious as to how that author then viewed those	14	
15	results, but, really, what I care about is the	15	
16	results.	16	
17	BY MR. SLATER:	17	
18	Q. Do you know whether that's what most	18	• •
19	gynecologists and urogynecologists do, or is that just	19	
20	your practice?	20	
21	A. I don't know.	21	
22	Q. Have you ever misrepresented the	22	
	rephrase.	23	• • • • • • • • • • • • • • • • • • • •
24	Have you ever misrepresented the results of	24	
25	any studies that you've performed in any peer-reviewed	25	relationship with Ethicon and met Ethicon people
	Page	59	Page 61
1			
۱ +	journal?	1	through him as well.
2	journal? A. Not that I know of.	1 2	•
			Q. When you first entered into your own
2	A. Not that I know of.	2	Q. When you first entered into your own personal consulting arrangement where you were going
2	A. Not that I know of.Q. How about in anything you've ever authored	3	Q. When you first entered into your own personal consulting arrangement where you were going to now start being paid money directly by Ethicon
2 3 4	A. Not that I know of. Q. How about in anything you've ever authored or co-authored?	3	Q. When you first entered into your own personal consulting arrangement where you were going to now start being paid money directly by Ethicon A. Yes.
2 3 4 5	A. Not that I know of.Q. How about in anything you've ever authored or co-authored?A. Not that I know of.	2 3 4 5	Q. When you first entered into your own personal consulting arrangement where you were going to now start being paid money directly by Ethicon A. Yes. Q was that in 2004?
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	Confidential - Subject to :	Page 62	LI	on and order or confidentiall	Page 6
1	continuously. There were certainly large periods of	rage 02	,	you'll gay though other that I con't tall you shout	rage o
	time where I never received a check from Ethicon.		1		
2			2	and then we'll cross that bridge.	
3	Q. When you say "large periods of time," was		3	A. Okay.	
4	there ever an entire year?		4	Q. Are there any that you can't tell me about?	
5	A. I think so.		5	A. Not that I know of.	
6	Q. What year?		6	Q. So we just wasted a minute.	
7	A. I couldn't tell you, but I don't think		7	MR. SNELL: I just wanted to be	
8	I've certainly within the last year I don't think		8	cautious, you know, obviously not go ahead. Answer	
9	I've received any money from Ethicon from a		9	the question.	
10	professional education standpoint, consulting.		10	BY MR. SLATER:	
11	Q. Is that because of the reduction in the use		11	Q. So tell me all of the medical device	
12	of Prolift® and then ultimately the Prolift® being		12	manufacturers, in addition to Ethicon, that you have	
13	removed from the market?		13	consulted for.	
14	MR. SNELL: Objection, form.		14	A. AMS, which stands for American Medical	
L5	THE WITNESS: Probably something to do		15	Systems.	
L6	with that and probably also with the fact that their		16	Q. Right. What was that in connection with?	
L7	slings have been out a long time. I think most people		17	A. That was in connection with doing an	
18	either learn to do them in residency now or learned it		18	investigational project regarding an attempt to create	
19	in the past.		19	a system to do the sacrocolpopexy procedure through a	
20	BY MR. SLATER:		20	transvaginal approach.	
21	Q. Over the years can you estimate for me the		21	I've also done consulting with Boston	
22	amount of money Ethicon has paid you?		22	Scientific.	
23	A. In total?		23	Q. What was that in connection with?	
24	Q. Yeah.		24	A. I many years ago, probably in 2005, 2006,	
25	A. I would guess somewhere in the range of		25	something like that, they wanted my input into one of	
		Page 63			Page
1	let's see. Eight years. Probably in the range of 80	1 480 00	1	their transvaginal mesh procedures for prolapse and	1 4.50
2	to \$100,000.		2	then more recently wanted, you know, to use my	
3	Q. In your career have you ever worked well,		3	opinions regarding some of their newer products.	
	rephrase.		4	And then I also believe that they came out	
5	Have you also consulted for companies other		5	with a prepubic sling as opposed to a retropubic	
6	than Ethicon?		6	sling, and I believe I did some consulting with them	
7	A. I have.		7	in regards to that.	
8	Q. Which others?		8	Q. Which product is that?A. I forget the name of it. It didn't really	
9	MR. SNELL: To the extent that they're		9		
10	not subject to a nondisclosure, you can answer that.		10	go very far.	
11	MR. SLATER: Well, I don't understand		11	Q. Any other manufacturers?	
L2	what that means. I mean, he has a CV where he		12	A. Yes. Coloplast. Would you like to know	
L3	makes he talks about and there's disclosures in		13	what I've done with them?	
L4	his published articles, so how can you say		14	Q. Sure.	
15	MR. SNELL: Obviously anything that's		15	A. Worked with them regarding their	
16	public, he can tell you about, but if it's not public,		16	sacrocolpopexy mesh and a well, maybe that's	
17	if it's subject to a Confidentiality Agreement, I		17	something I basically a stent, a vaginal stent to	
18	don't want him to answer that question, but if it's		18	help do the sacrocolpopexy.	
L9	not, obviously, he should tell you.		19	And then I've also worked with Bard. I was	
20	BY MR. SLATER:		20	a research site for Bard regarding the adjust sling.	
21	Q. Well, this is what I'd like to do: Tell me		21	Q. That's an SUI sling?	
22	all the other medical device manufacturers or		22	A. Correct.	
23	pharmaceutical companies you've also consulted with,		23	Q. So during your career you have consulted for	
24	and if there are ones that you don't want to tell me		24	Ethicon, and you estimate you were paid 80 to \$100,000 $$	
	about because you think that you're not allowed to,		25	during this entire period of time?	
25	about because you timik that you're not anowed to,		25	daring and entire period of time.	

	Confidencial Babyccc to Ber				(0
1	A. Yeah, that may be an overestimation because,	age 66	1		age 68
	again, I was sort of doing it what might I make in an		2	achieve without having to use synthetic mesh; you	
2	average year, but, again, there have been years where			prefer not to have to use it, right?	
3			3	MR. SNELL: Objection, form.	
4	I probably haven't done much, so it may be a low as		4	•	
5	50, but I don't really know.		5	THE WITNESS: I would prefer that I	
6	Q. You realize all that documentation was		6	could wave a magic wand over a woman's pelvis and make	
7	produced to us, right?		7	it better.	
8	A. I don't realize that.		8	BY MR. SLATER:	
9	Q. Yeah, it		9	Q. You would prefer that, all things being	
10	A. I would like to see it.		10	equal, you not have to put synthetic mesh, which is a	
11	Q. Because, okay, I think that you're		11	foreign body, into a woman's pelvis if you didn't need	
12	underestimating, but that's fine.		12	to, right?	
13	So in your career you've		13	MR. SNELL: Same objection, form.	
14	MR. SNELL: Move to strike. You're		14	THE WITNESS: I don't really know how	
15	asking him his best estimate. Let's not be		15	to answer that. I mean, I prefer to never expose a	
16	ridiculous.		16	woman to any risk.	
17	MR. SLATER: Let's not be ridiculous?		17	BY MR. SLATER:	
18	I'm trying to refresh his recollection.		18	Q. You would agree with me that if there were	
19	MR. SNELL: Show it to him then. Don't		19	two procedures that have roughly the same level of	
20	sit there and try to insult him say, you know		20	efficacy but one of the procedures has higher levels	
21	MR. SLATER: I'm not trying to insult		21	of risk, you should choose the procedure that has the	
22	him.		22	lower level of risk, correct?	
23	MR. SNELL: you're underestimating.		23	MR. SNELL: Objection, form.	
24	He told you his best estimate.		24	THE WITNESS: I'm always I would	
25	MR. SLATER: Can I keep going?		25	always want to give patients the procedure that had	
	D.	000 67		Th.	000 60
1		age 67	1		age 69
1 2	MR. SNELL: Yeah, go ahead.	age 67		the best chance of working with the lowest chance of	age 69
2	MR. SNELL: Yeah, go ahead. BY MR. SLATER:	age 67	2	the best chance of working with the lowest chance of risk, yes.	age 69
2 3	MR. SNELL: Yeah, go ahead. BY MR. SLATER: Q. In your career you have consulted for	age 67	2	the best chance of working with the lowest chance of risk, yes. BY MR. SLATER:	age 69
2 3 4	MR. SNELL: Yeah, go ahead. BY MR. SLATER: Q. In your career you have consulted for Ethicon, correct?	age 67	2 3 4	the best chance of working with the lowest chance of risk, yes. BY MR. SLATER: Q. If there were two procedures available to	age 69
2 3 4 5	MR. SNELL: Yeah, go ahead. BY MR. SLATER: Q. In your career you have consulted for Ethicon, correct? A. Correct.	age 67	2 3 4 5	the best chance of working with the lowest chance of risk, yes. BY MR. SLATER: Q. If there were two procedures available to you to treat prolapse and the level of efficacy	age 69
2 3 4 5 6	MR. SNELL: Yeah, go ahead. BY MR. SLATER: Q. In your career you have consulted for Ethicon, correct? A. Correct. Q. In your career you have consulted for	age 67	2 3 4 5 6	the best chance of working with the lowest chance of risk, yes. BY MR. SLATER: Q. If there were two procedures available to you to treat prolapse and the level of efficacy between the two, and I'm not talking about anatomic,	age 69
2 3 4 5 6 7	MR. SNELL: Yeah, go ahead. BY MR. SLATER: Q. In your career you have consulted for Ethicon, correct? A. Correct. Q. In your career you have consulted for additional medical device manufacturers, including	age 67	2 3 4 5 6 7	the best chance of working with the lowest chance of risk, yes. BY MR. SLATER: Q. If there were two procedures available to you to treat prolapse and the level of efficacy between the two, and I'm not talking about anatomic, I'm talking about functional in terms of what the	age 69
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		Page 70			Page 72
	1	BY MR. SLATER:	1	part of how we assess outcomes, they're very	
	2	Q. You're familiar with the Altman study	2	important, they're also pretty nonspecific in many	
	3	published in 2011 in the New England Journal of	3	cases. And if a recurrence if there is going to be	
	4	Medicine, correct?	4	a higher rate of recurrence with one group versus the	
	5	A. I am.	5	other and that's subsequently a year after the study	
	6	Q. You're familiar with the fact that from a	6	is concluded is going to require someone to have	
	7	functional outcome perspective, the outcomes between	7	another surgery because their prolapse procedure	
	8	the colporrhaphy and the Prolift® groups were	8	failed, then that would definitely figure into which	
	9	essentially the same, right?	9	one I'd want to choose.	
	10	MR. SNELL: Objection to form.	10	BY MR. SLATER:	
	11	THE WITNESS: I would disagree with	11	Q. You would agree with me that the evaluation	
	12	that statement.	12	of what is important about a recurrence has evolved	
	13	BY MR. SLATER:	13	and changed over the years in your field, correct?	
	14	Q. Well, you would agree that the authors did	14	A. Correct.	
	15	not feel there was any significant difference overall	15	Q. Back around 2000, 2001 the focus was	
	16	in terms of the functional outcomes between the	16	basically 100% or close to 100% on anatomic	
	17	colporrhaphy and the Prolift® groups; wouldn't you	17	recurrence, correct?	
	18	agree with that?	18	A. I would say in the '90s it was more around	
	19	MR. SNELL: Objection to form.	19	100%. Right around that time is when people really	
	20	THE WITNESS: I would not agree with	20	started wanting to incorporate quality of life	
	21	that. The primary endpoint was a subjective sense of	21	outcomes into their studies.	
	22	no longer feeling a bulge. That was part of the	22	Q. And there were articles that started to get	
	23	primary endpoint, and that was significantly different	23	published in the early 2000s where respected authors	
	24	between the two groups.	24	like people like Anne Weber started to say, hey, you	
	25	BY MR. SLATER:	25	know, maybe we need to start looking not just at	
-		Page 71			Page 73
		Page 71	1	anatomic evaluation but we have to start looking at	Page 73
	1	Q. In terms of the two groups, the colporrhaphy	1 2	anatomic evaluation but we have to start looking at function and quality of life because I think we're	Page 73
	1 2	Q. In terms of the two groups, the colporrhaphy and the Prolift®, the quality of life measures were	2	function and quality of life because I think we're	Page 73
	1 2 3	Q. In terms of the two groups, the colporrhaphy and the Prolift®, the quality of life measures were essentially the same, according to what the authors	2 3	function and quality of life because I think we're neglecting to look at that.	Page 73
	1 2 3 4	Q. In terms of the two groups, the colporrhaphy and the Prolift®, the quality of life measures were essentially the same, according to what the authors concluded, correct?	2	function and quality of life because I think we're	Page 73
	1 2 3 4 5	Q. In terms of the two groups, the colporrhaphy and the Prolift®, the quality of life measures were essentially the same, according to what the authors concluded, correct? A. So you are talking about specific quality of	2 3 4 5	function and quality of life because I think we're neglecting to look at that. You would agree with that statement, correct?	Page 73
	1 2 3 4	Q. In terms of the two groups, the colporrhaphy and the Prolift®, the quality of life measures were essentially the same, according to what the authors concluded, correct? A. So you are talking about specific quality of life instruments like POP-DI, those types of things?	2 3 4	function and quality of life because I think we're neglecting to look at that. You would agree with that statement, correct? MR. SNELL: Objection to form. Go	Page 73
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			on and order or confractional	
	Page 74			Page 76
	years ago.	1	•	
2	Q. You would agree with me that when you look	2	Q. Was an important part of Vincent Lucente's	
3	at anatomic outcome alone, that doesn't give enough of	3	professional time devoted to the consulting work and	
4	a picture to determine whether or not a recurrence is	4	the speaking work he did on behalf of Ethicon during	
5	really significant to the patient, correct?	5	the time the Prolift® was on the market?	
6	A. Yes, I'd agree with that.	6	MR. SNELL: Objection, form.	
7	Q. And to give you an example, you could get	7	THE WITNESS: Can you repeat. You said	
8	somebody to a stage zero and have everything right	8	a word in terms of the degree of it. I forget what it	
9	where it belongs, if you were to put together a	9	was.	
10	perfect anatomic model, and for many women that would	10	BY MR. SLATER:	
11	actually be incredibly uncomfortable, correct?	11	Q. Well, let me ask you this: Was a	
12	A. Correct.	12	significant part of Vincent Lucente's professional	
13	Q. Based on your experience, how would you	13	work, from your perspective being his partner	
14	describe your partner, Vincent Lucente's role with	14	A. Yes.	
15	Ethicon in connection with the Prolift®?	15	Q devoted to the Prolift®?	
16	A. My understanding is that he was one of the	16	A. There was I'm not trying to give you a	
17	first US doctors to travel to France to learn the TVM	17	hard time. He did a fair amount of talking and things	
18	procedure, which is the precursor to Prolift®. I	18	like that. I wouldn't say that that was most of his	
19	don't know how many other US doctors went and did	19	work, but in his work, he did a lot of training, where	
20	that. I certainly know that he was one. I can't	20	he would do the surgery and people would come and	
21	imagine they sent 100. And he certainly trained many	21	learn about the surgery while he was doing it, so it	
22	doctors in the United States on doing the procedure.	22	was a combination of those two things.	
23	Q. Did Vincent Lucente speak on a regular basis	23	Q. Did yourself and Dr. Lucente socialize with	
24	to other physicians at professional meetings and	24	people from Ethicon?	
25	events like that about the benefits of the Prolift®?	25	A. Yes.	
	Page 75			Page 77
1	Page 75 A. I think that's a fair assessment, yeah.	1	Q. Attend dinners with people from Ethicon?	Page 77
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	Confidencial - Subject to Scipula	LLI	on and order or contradictally	
1	Page 78	,	COSA	Page 80
	that, you know, bring the product to the hospitals		A. Yes.	
2	that I work in.	2		
3	Q. How about people in the marketing	3	Q. Is Murphy-2 your supplemental report in this	
4	department?		litigation?	
5	A. Again, I don't know who is in the marketing	5	A. Yes.	
6	department and who is not. They don't necessarily	6	Q. Is this the only supplemental report you	
7		7		
8	Q. Did you, before the Prolift® became	8	A. Yes.	
9	available, utilize Gynemesh® PS to treat prolapse	9	Q. You set forth three numbered opinions in	
LO	where you would cut it and then implant it through the	10	your supplemental report. Do you see that?	
L1		11	A. Yes.	
L2	A. Not well, yes, I did do some of that	12	Q. Are those the three additional opinions that	
L 3	before Prolift®.	13	you documented having formed since the writing of your	
L4	Q. Can you quantify for me to what extent you	14	initial report?	
L5	were doing that?	15	A. Yes.	
L6	A. Maybe 30 to 50 cases, something like that.	16	Q. Now, you indicate in the supplemental report	
.7	Q. Total?	17	that you reviewed additional Ethicon funded studies.	
8	A. Rough estimate.	18	When you say that, are you saying you	
L9	Yes.	19	reviewed the actual well, rephrase.	
20	Q. Once the Prolift® came out, did you at any	20	When you say that you reviewed additional	
21	point	21	Ethicon funded studies, what are you referring to?	
22	MR. SNELL: I'm sorry. Can you read	22	A. I'm referring to work that was back from the	
23	back the question.	23	time of TVM.	
24	MR. SLATER: I asked him how many times	24	Q. What specific documents were you looking at?	
25	he used Gynemesh® before the Prolift® came out to	25	A. I don't recall.	
	Page 79			Page 8
1	treat prolapse through the vagina.	1	Q. You say you reviewed mesh studies to repair	1 age o
2	MR. SNELL: Through the vagina, okay,	2	pelvic organ prolapse. Is that something different	
3	that was the question. I didn't know if you were	3	from the additional Ethicon funded studies, or is that	
	including abdominal. Was it transvaginally? That's	4	just another description of the same thing?	
	fine, go ahead.	5	A. I think looking at other studies in terms of	
	BY MR. SLATER:		histology, things of that nature.	
7	Q. Once the Prolift® came out, did you ever use	7	Q. What studies are you referring to there?	
8	Gynemesh® PS, just that product, where you cut it and	8	A. Again, I don't recall.	
	put it in through the vagina to treat prolapse?	9	Q. You say you reviewed Axel Arnaud's	
9			• • • • • • • • • • • • • • • • • • • •	
10	A. No. I actually I think stopped doing that	10	deposition.	
L1	before Prolift® came out.	11	Did you read the deposition?	
12	Q. Why was that?	12	A. Again, very cursory.	
L3	A. With the exception of I also did Prosima	13	Q. When you say "cursory," how much time did	
L4	afterwards.		you spend?	
L5	Q. Why was it that you stopped using Gynemesh®	15	A. Probably 15 minutes.	
L6	through the vagina?	16	Q. Okay. Was there anything of significance	
L7	A. Because the way I had been using it was a	17	you saw when you read Axel Arnaud's well, rephrase.	
L8	non-anchored way, and I just thought that running it	18	When you made your cursory review of Axel	
L9	through the tissues provided better support.	19	Arnaud's deposition for about 15 minutes, was there	
20	(Document marked for identification	20	anything you saw that was of any significance to you	
	as Murphy Deposition Exhibit No. 2.)	21	that you can relate to me right now?	
21		1		
	BY MR. SLATER:	22	A. Not that I can recall.	
22	BY MR. SLATER: Q. Hand you an exhibit marked as Murphy-2.	22	A. Not that I can recall.Q. How was it that a cursory 15-minute review	
22 23			Q. How was it that a cursory 15-minute review of Axel Arnaud's deposition led you to say that that	
21 22 23 24 25	Q. Hand you an exhibit marked as Murphy-2.	23	Q. How was it that a cursory 15-minute review	

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	Page 82			Page 84
1	A. Well, it's not just Axel Arnaud's	1	MR. SNELL: Object to form.	
2	deposition.	2	THE WITNESS: Correct.	
3	Q. I just want to what I'm asking is that	3	BY MR. SLATER:	
4	component. I'll reask the question.	4	Q. You say in your opinion Number 1 well,	
5	You say that after the first sentence of	5	let me ask you this well, rephrase.	
6	rephrase.	6	In Opinion Number 1 here in your	
7	After the first sentence of your	7	supplemental report you say, "Ethicon properly studied	
8	supplemental report where you say, I have reviewed the	8	and funded studies to support its use of the Gynemesh®	
9	additional Ethicon funded studies, mesh studies to	9	PS mesh used in Prolift®."	
10	repair pelvic organ prolapse and Axel Arnaud's	10	Do you see that?	
11	deposition, the next sentence you say, these studies	11	A. Yes.	
12	and testimony further support my opinions in my	12	Q. What is the specific basis for what you're	
13	initial report, including but not limited to those	13	referring to there to support that opinion?	
14	below.	14	A. I believe that the some of the TVM work	
15	You see that?	15	was funded by Ethicon.	
16	A. Yes.	16	Q. When you say that Ethicon properly studied	
17	Q. How was it that your cursory 15-minute	17	and funded studies to support its use of the Gynemesh®	
18	reading of Axel Arnaud's deposition, how did that	18	PS mesh used in Prolift®, what specifically about the	
19	component further support your opinions?	19	TVM study, if that's what you're referring to, are you	
20	A. I don't have an answer for you.	20	relying on for that opinion?	
21	Q. How is it that the additional Ethicon funded	21	A. I'm sorry, I lost you.	
22	studies, whatever they were, specifically further	22	Q. That Opinion Number 1, you're saying that's	
23	supported your opinions?	23	a reference to the TVM study?	
24	A. The answer to that is that it was not that I	24	A. Yes.	
25	read something ground shaking in those extra reports.	25	Q. What specifically about the TVM study are	
-		_		
	Page 83			Page 85
	It was that these are opinions that I thought, given		you relying on to say that Ethicon properly studied	Page 85
	It was that these are opinions that I thought, given the other testimonies from depositions and reports	2	the use of Gynemesh® PS for use in the Prolift®?	Page 85
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	they're certainly higher than what we see with		back to your Opinion Number 1, when you refer to	
2	Prolift® or at least in my practice at this time. I	2	Ethicon properly studied and funded studies to	
3	know there were, you know, multicenter studies, and	3	supports its use of the Gynemesh® PS mesh used in	
4	some studies had quite high erosion rates. Other	4	Prolift®, you're talking about the TVM study, correct?	
5	centers had very low erosion rates.	5	A. That's one of the things I'm referring to as	
6	Q. The erosion rates documented in the TVM	6	well.	
7	study are high rates of erosion and exposure, correct?	7	Q. Well, is there something else you're	
8	MR. SNELL: Objection, form.	8	referring to?	
9	THE WITNESS: Compared to what I've	9	A. Not that I'm recalling right now.	
L O	seen in my practice, yes.	10	Q. And when you say they properly funded it,	
11	BY MR. SLATER:	11	what are you referring to? Do you have some knowledge	
L 2	Q. You certainly wouldn't take those rates of	12	about the funding for the TVM study?	
L 3	exposure that were demonstrated in the TVM study and	13	A. It's just my understanding. I don't have	
L 4	tell a patient based on that, there's only a small	14	any documentation.	
L 5	risk of exposure into the vagina; you'd agree with	15	Q. You have no support for that statement, do	
L6	that statement, right?		you?	
L7	MR. SNELL: Objection, form.	17	A. No, because when an abstract is published,	
L 7	THE WITNESS: Not necessarily. Because	18	they don't have to necessarily write funding, things	
L 0 L 9	the risk might be small, meaning if it happens, it's		like that.	
	not that bad an outcome. It's something that can		Q. All I'm asking is you say that Ethicon	
20		20		
21	usually be pretty easily addressed, but I would not	21	properly funded, here you're talking about the TVM	
22	consider 30% erosion rate to be a small risk.	22	study	
23	BY MR. SLATER:	23	A. Right.	
24	Q. You would not consider a 20% erosion rate to	24	Q but you have no basis to say what funding	
25	be a small risk?	25	they put into play for that, right? You have no idea	
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	Page 87			Page 8
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	Confidential - Subject to St	_	CI	on and order or confractionality	1
		Page 90			Page 92
	were also studies on Gynemesh® PS, not in TVM as well.		1		
2	Q. Let's talk about. I'm trying to limit this		2	Q. Who are the members of the French TVM group;	
3	to TVM to begin with.		3	·	
4	A. Okay.		4	A. I know some of them.	
5	Q. So with regard to TVM, what specific		5	Q. If you weren't going to look at the list of	
6	documentation are you relying on to say that Ethicon		6	their names on those articles, would you know?	
7	properly studied the use of Gynemesh® PS in the		7	A. I would think Cosson, Jacquetin, I think	
8	Prolift®? You said abstracts that you think were		8	Debodinance, Collinet. Those are the ones that come	
9	published somewhere around 2004, 2005. Anything else		9	to mind. And I never took French, so if I'm	
10	specifically document-wise that you're relying on for		10	mispronouncing the names, I apologize to them.	
11	that opinion?		11	Q. Do you feel that the conclusions in the	
12	A. Let me look through the references.		12	articles published by the French TVM group with regard	
13	(Witness reviews document.)		13	to the TVM procedure which ultimately became the	
14	I believe the de Tayrac study here used		14	Prolift® procedure are an important source of	
15	Gynemesh®, the 2002.		15	information about the Prolift®?	
16	Q. Was that part of the TVM study because		16	A. Yes.	
17	that's what we're asking about right now? Is what are		17	Q. Let's talk about the TVM study a little bit.	
18	you talking about with regard to the TVM study?		18	Do you know what the primary outcome measure	
19	A. You know, as an American, I wasn't		19	was, the primary endpoint was?	
20	necessarily sure who exactly was in the, quote, TVM		20	A. If I recall correctly, it was less than or	
21	group or not. He may not have been.		21	equal to Stage 1 POP-Q.	
22	And I think I had already referenced the		22	Q. Do you have an understanding of what the	
23	published TVM data in my initial report, for instance,		23	percentage of recurrence was set down as in order to	
24	the Miller study from 2011.		24	meet or fail the primary endpoint?	
25	Q. You mean the Miller article from 2011,		25	A. I believe they wanted to show that there was	
		Dago 01			Daga 03
1		Page 91	1		Page 93
	correct?	Page 91	1	not greater than 20% failure.	Page 93
2	correct? A. Yes. Sorry.	Page 91	2	not greater than 20% failure. Q. Do you know whether the French study met	Page 93
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		Page 94			Page 96
1	especially a prospective study, you want to have an		1	because it is a somewhat complex system. I don't find	
2	endpoint, doesn't mean it's necessarily a perfect		2	it that complex, but a lot of people do. And someone	
3	endpoint.		3	may have mentioned that there was an issue during the	
4	Q. Generally, when in a study like the TVM		4	TVM study along the same lines, but I don't recall for	
5	study when an endpoint is chosen, if it doesn't if		5	sure.	
6	the study does not meet the endpoint, should that be		6	BY MR. SLATER:	
7	any significance to the people running the study, or		7	Q. Have you ever reviewed any document with	
8	can they say, well, no big deal, we just made up the		8	regard to whether or to what extent there were errors	
9	number anyway?		9	with the POP-Q measurements in the French or US TVM	
10	MR. SNELL: Objection, form.		10	studies?	
11	BY MR. SLATER:		11	A. Not that I recall.	
12	Q. How does that work?		12	Q. You would agree with me if there was a	
13	MR. SNELL: Objection, form.		13	systemic problem with errors with the POP-Q	
14	THE WITNESS: I think actually what you		14	measurements, that would cast doubt on the validity of	
15	said is pretty good. It should matter, but to a		15	the data that was reported with regard to recurrences,	
16	certain extent, you have to take it in context that it		16	correct?	
17	was a somewhat arbitrary endpoint.		17	A. Sure.	
18	BY MR. SLATER:		18	MR. SNELL: Objection, form.	
19	Q. What, if any, reaction did Ethicon have to		19	BY MR. SLATER:	
20	whether or not the endpoints were met in the French		20	Q. And to the extent that there were errors in	
21	and US TVM studies?		21	the POP-Q measurements with the TVM study, you're not	
22	A. I don't know.		22	in a position to give me any information on that right	
23	Q. Do you know what the actual recurrence rates		23	now, other than that you generally heard there might	
24	were that were found in the US and French TVM studies?		24	have been some issues when you were doing your own	
25	A. I think the recurrence rate in the at		25	study years later?	
	Ī	Page 95			Page 97
1		Page 95	1	A Correct	Page 97
	what year are we talking about?	Page 95	1 2	A. Correct. O. So, as you sit here now, you can't offer me	Page 97
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	Pa	age 98		Pa	age 100
1	with Prolift®. I'm sorry. Some of it runs together.		1	BY MR. SLATER:	
2	But that, you know, any time had you to do a		2	Q. You certainly would have wanted Ethicon to	
3	multicenter study and you find different results using		3	try to determine why the differences in exposure rates	
4	the same procedure, similar types of patients and you		4	existed from center to center, right?	
5	see differences, you try and determine, you know,		5	MR. SNELL: Objection, form.	
6	maybe why one group had a higher rate than the other.		6	BY MR. SLATER:	
7	Q. You would agree with me with regard to the		7	Q. Sitting here as an expert witness, giving	
8	TVM study that to the extent there were differences in		8	opinions about Ethicon's conduct, overall, you would	
9	exposure rates from hospital to hospital, it would		9	say they should have done that, right?	
10	have been important for Ethicon to find out why that		10	A. I think that	
11	existed in case that would have some impact on patient		11	MR. SNELL: Objection, form. Go ahead.	
12	selection, correct?		12	THE WITNESS: the physicians running	
13	MR. SNELL: Objection.		13	the study that would be something that they would have	
14	BY MR. SLATER:		14	wanted to look at. It might be hard to study that,	
15	Q. That would be one factor you'd want to look		15	though.	
16			16	BY MR. SLATER:	
17	MR. SNELL: Objection, form. Go ahead.		17	Q. Well, Ethicon funded the study, correct?	
18	THE WITNESS: Yes.		18	A. Again, I'm not positive of that. I think	
19	BY MR. SLATER:		19	they funded it to some degree.	
20	Q. Another thing you'd want to look at is there		20	Q. Do you know who owned the data from the TVM	
	any sort of factor that led to these differences that			studies, whether the data was owned by Ethicon or by	
21	•		21	the investigators?	
22	you would want to warn physicians and patients about;		22	· ·	
23	that'd be another reason to want to learn that,		23	A. I do not, no.	
24			24	Q. Assuming that Ethicon owned the data, you	
25	A. I'm sorry, factors, is that what you said?		25	would expect that Ethicon would have taken steps to	
	Pa	age 99		Pa	Page 101
1	Q. A factor. You want me to reask the	age 99	1	Pa figure out why are we seeing these variances in	Page 101
1 2		age 99	1 2		Page 101
	Q. A factor. You want me to reask the	age 99		figure out why are we seeing these variances in	Page 101
2	Q. A factor. You want me to reask the question?	age 99	2	figure out why are we seeing these variances in exposure rates from center to center before we are	age 101
2 3	Q. A factor. You want me to reask the question?A. Yes.	age 99	2	figure out why are we seeing these variances in exposure rates from center to center before we are going to now put this procedure out on the market for	age 101
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	Confidential - Subject to		LI	on and Order of Confidentiality
		Page 102		Page 10
	there was a physician's technique at one particular		1	A. I'm not.
2	center that was leading to a much higher erosion rate,		2	Q. Are you familiar with the term FMEA, failure
3	•		3	modes and effects analysis?
4	know so they could make sure that they give the right		4	A. No.
5	instructions in their surgical technique and make sure		5	Q. And DDSA, just for the record, device design
6	the professional education is geared to prevent that,		6	safety assessment, is that a term you're familiar
7	right?		7	with?
8	MR. SNELL: Objection, form.		8	A. No.
9	THE WITNESS: I can't say to what		9	Q. Did you look at the DDSA or FMEA analyses
10	Ethicon would have liked but I believe a paper to that		10	for the Prolift® in this case?
11	effect was published looking at risk factors during		11	A. I did not.
12	TVM such as T incision and hysterectomy. That was		12	Q. And you're not going to offer any opinions
13	published.		13	on that subject at all, correct? If you didn't look
14	BY MR. SLATER:		14	at them, you're not going to offer opinions, right?
15	Q. My question is with regard to differences in		15	A. If you show it to me, I guess maybe I would,
16	exposure erosion rates between the different centers.		16	but, otherwise, no, I'm not going to offer them in my
17	If it turned out if they actually did study the		17	report.
18	question and it turned out that there was a technique		18	Q. It's not something you've ever done, as we
	issue, you would want to be able to study it,			sit here now, right?
19			19	
20	establish that and then incorporate that information		20	A. No.
21	into your instructions and professional education,		21	Q. Have you ever been involved in authoring a
22	right?		22	clinical expert report within a medical device company
23	MR. SNELL: Objection, form.		23	with regard to a medical device that was going to be
24	THE WITNESS: That would be a nice		24	on the market or was already on the market?
25	thing to have.		25	A. A clinical device
		Page 103		Page 10
1	BY MR. SLATER:		1	Q. Clinical expert report; do you know what
2	Q. You've never worked directly at a medical		2	that is?
3	device company, correct?		3	A. No.
4	A. Correct.		4	Q. To your recollection, did you review the
5	Q. Never worked at a pharmaceutical company,		5	clinical expert reports for the Prolift®?
6	correct?		6	A. No.
7	A. Correct.		7	Q. You're not going to offer any opinions on
8	Q. You've never been involved in a design		8	that subject, or you haven't yet, right?
9	control process prelaunch of a medical device,		9	A. Correct.
9 10			10	Q. You don't intend to, as you sit here now,
	A. I've been involved in I think they called			
11	·			right? A. Unless you ask me about it and show me the
12	it a validation study for TVT-Secur®. They had me		12	A. Unless you ask me about it and show me the
13	come in and look at jeez, it's been many years, but		⊥3	report.
1 4	· · ·		, ,	O Thomas von 1 f:1!'
	I think it was along the lines of wanting to		14	Q. There's no you have no familiarity, as
15	I think it was along the lines of wanting to standardize technique so that it can be, you know,		15	you sit here now, with the clinical expert report for
15	I think it was along the lines of wanting to standardize technique so that it can be, you know, printed in the IFU, things like that. I think it was			you sit here now, with the clinical expert report for the Prolift®, and you have no opinions, as you sit
15 16	I think it was along the lines of wanting to standardize technique so that it can be, you know, printed in the IFU, things like that. I think it was along those lines, but I was not I was a consultant		15	you sit here now, with the clinical expert report for the Prolift®, and you have no opinions, as you sit here now on it, correct?
15 16 17	I think it was along the lines of wanting to standardize technique so that it can be, you know, printed in the IFU, things like that. I think it was		15 16	you sit here now, with the clinical expert report for the Prolift®, and you have no opinions, as you sit
15 16 17 18	I think it was along the lines of wanting to standardize technique so that it can be, you know, printed in the IFU, things like that. I think it was along those lines, but I was not I was a consultant		15 16 17	you sit here now, with the clinical expert report for the Prolift®, and you have no opinions, as you sit here now on it, correct?
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14 15 16 17 18 19 20 21 22 23 24	I think it was along the lines of wanting to standardize technique so that it can be, you know, printed in the IFU, things like that. I think it was along those lines, but I was not I was a consultant at that point. I was not employed. Q. You've never been involved in structuring or implementing a design control process for a medical device from the medical device company perspective, correct? A. No. I don't really even know what design		15 16 17 18 19 20 21 22 23	you sit here now, with the clinical expert report for the Prolift®, and you have no opinions, as you sit here now on it, correct? A. I've never read it. MR. SNELL: Objection, form. BY MR. SLATER: Q. You've never read it, so you wouldn't expect to be offering opinions, correct?

	Page 10			Page 108
1	saying you haven't read it and have no opinions now, I		what was reported in the articles that you read is	rage 106
	will not be giving it to you.	1		
2	A. Okay.	2	underlying data?	
3 4	Q. Unless you want to really stay late tonight.	3	A. And when you say "the underlying data," what	
5	To your knowledge, were the exposure rates	5	are you referring to?	
6	in the French and US TVM study accurately counted or	6	Q. The case specific patient specific forms	
7	undercounted? Do you have any information one way or	7		
8	the other on that?	8	what was recorded with regard to whether or not an	
	A. I do not.	9	exposure existed at a certain time.	
9	Q. That's not something you tend to offer	10	A. Right. I have not to save us some time	
11		11	maybe, I have not reviewed any case report forms that	
12	A. I tend to offer opinions on whether or not I	12	the physicians or the patients filled out. I have not	
13	believe what I see is published or presented at	13	reviewed their database. I have not reviewed their	
14	meetings.	14	you know, their SAS database or anything like that. I	
15	Q. Without looking at the underlying data and	15	did not have any access to the primary data, only what	
16	studying that question, you're not in a position, as	16	was published.	
	you sit here now, to offer an opinion on whether or		Q. Okay. So you wouldn't be forming an opinion	
17	not the exposures that occurred in the French and US	17	about whether or not the published data reflects what	
19	TVM studies were accurately reported in the published	19	the actual raw data in the case specific forms shows,	
20	manuscripts, correct?	20	correct?	
21	MR. SNELL: Objection, form.	21	MR. SNELL: Objection, form.	
22	THE WITNESS: I guess I'd have trouble	22	THE WITNESS: Only to what I just	
23	agreeing to that. I mean, most doctors that I know	23	responded before, that I tend to trust doctors that do	
24	that dedicate their time to taking care of people and	24	this work.	
25	going through the trouble of producing research, and I	25	BY MR. SLATER:	
25	going amough the trouble of producing research, and r	23	DI MIK BEHTEK.	
	Page 10'	·		Page 109
	1 age 10			υ
1	tend to believe what they produce, but I wasn't there	1	Q. You tend to trust when something is	C
1 2				C
	tend to believe what they produce, but I wasn't there	1	•	Ü
2	tend to believe what they produce, but I wasn't there standing next to them when they looked to see whether	1 2	published or presented at a meeting, you tend to trust	
2 3 4	tend to believe what they produce, but I wasn't there standing next to them when they looked to see whether or not there was an exposure and checked off on the	1 2 3	published or presented at a meeting, you tend to trust that the data being given is accurate, right?	
2 3 4	tend to believe what they produce, but I wasn't there standing next to them when they looked to see whether or not there was an exposure and checked off on the sheet.	1 2 3 4	published or presented at a meeting, you tend to trust that the data being given is accurate, right? A. Correct.	
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	Confidencial - Subject to Scipula	CI		
	Page 110			Page 112
1	Ethicon's perspective, what, if any, reliance was	1	because it's not something you've looked at, right?	
2	placed on the TVM studies?	2	A. Yes, only to it's the same question you	
3	A. I do not know.	3	asked before in terms of only to the extent that I	
4	Q. Let me ask you about the Gynemesh® PS study.	4	it's my opinion that I tend to trust that.	
5	Do you know what that is?	5	Q. Your assumption is that the reported results	
6	A. I know that a study was reported in terms of	6	would be accurate, but you've never actually looked at	
7	abstract form on the use of Gynemesh® if that's the	7	it yourself to confirm that?	
8	one you're referring to.	8	A. Correct.	
9	Q. Do you know any specific information about,	9	Q. And you're not in a position to form a	
10	for example, how the Gynemesh® was used in that study?	10	specific opinion about whether it's correct. All you	
11	A. I believe it was used both transabdominally	11	have is your assumption, which is a general assumption	
12	and transvaginally.	12	that people will only accurately report data?	
13	Q. Have you looked at any of the underlying	13	MR. SNELL: Object to form.	
14	data, patient report forms or any of that with regard	14	THE WITNESS: Correct.	
15	to Gynemesh® PS study?	15	BY MR. SLATER:	
16	A. No.	16	Q. Do you know whether or to what extent	
17	Q. So you're not in a position to form any	17	Ethicon relied on or utilized the Gynemesh® PS study	
18	opinions about whether what is actually reported in	18	in connection with the Prolift®?	
19	the abstract or the white paper or the actual	19	A. I do not know what Ethicon relied upon.	
20	documents that were produced following the Gynemesh®	20	Q. Do you know what Ethicon relied on before it	
21	PS study about whether that accurately reflects what	21	marketed the Prolift® to make the decision the	
22	the data shows?	22	Prolift® is safe and effective and should be released	
23	A. I will go back to my previous answer, only	23	for marketing to the public?	
	in that I tend to trust that what I'm seeing published	24	A. As we stated earlier, I've never been an	
	is valid.	25	employee of Ethicon. I never worked in there. I	
			1 7	
	Page 111			Page 113
1	Page 111 Q. Beyond that you have never looked at the	1	never went to their meetings about how they were	Page 113
1 2		1 2	never went to their meetings about how they were deciding whether how to release Prolift®.	Page 113
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	-	LLI	on and order of confidentiality	
	Page 114		Page	116
1	Q. That's just an assumption you're forming?	1	package, I look at it as quickly as I can to determine	
2	A. It's an educated assumption.	2	how important it is for me to read this through and	
3	Q. Do you know what data was available to	3	then try and use my time. I'm a fully practicing	
4	Ethicon at the time the decision was made that the	4	physician with two kids. I have not read every word	
5	Prolift® is safe and effective to be marketed?	5	of everything that was presented here.	
6	A. I'm sorry. Could you repeat the question.	6	Q. Is there anything here in this list of	
7	Q. Sure. Do you know what specific data was	7	materials that you can tell me, yes, I know I read	
8	available to Ethicon as of February, March 2005 when	8	that in its entirety?	
9	they were actually now launching the Prolift®, what	9	A. No.	
10	they actually were relying on at the time they made	10	Q. Are there some of these materials that you	
11	the decision, yes, it's safe and effective, yes, we	11	have not read at all?	
12	can market it?	12	A. I'm sorry. Can I take that back?	
13	A. I do not know what they were relying on.	13	Q. Sure.	
14	Q. Since you don't know specifically what	14	A. I think that I read all of Michael Margolis'	
15	they're relying on, you're not going to offer any	15	deposition, and I think that I read all of Daniel	
16	specific opinions about whether that data was	16	Elliott's deposition. I think that's the only thing	
17	sufficient or not; fair statement?	17	I've read in its entirety.	
18	MR. SNELL: Objection, form.	18	Q. Did you read Vincent Lucente's deposition?	
19	THE WITNESS: I'm happy to offer	19	A. No. I only got about many 10% of the way	
20	opinions on the data that was present. I'm not going	20	through it.	
21	to make an expert opinion as to what Ethicon was	21	Q. Did you talk to him about his deposition?	
22	relying on. I have no idea what they thought was	22	A. I talked to him briefly about how it went.	
23	important.	23	Q. What did he tell you?	
24	BY MR. SLATER:	24	A. He told me that it went pretty well.	
25	Q. My question is this: Since you don't know	25	Q. Do you and Vincent Lucente, in your	
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1	Page 115		Page	117
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		e 118	Page 12
1	cases were. I don't know that there were any specific	1	•
2	disagreements as to why that might be or might not be,	2	
3	but I think that's a fair assessment of the	3	
4	differences between he and I.	4	
5	Q. What is your well, rephrase.	5	
6	During the time you've used the Prolift®,	6	
7	did your patient selection criteria change over the	7	7 A. Correct.
8	years?	8	· · · · · · · · · · · · · · · · · · ·
9	A. Not substantially, I don't think.	٥	read in the literature, correct?
10	Q. Did your understanding of which patient	10) A. Correct.
11	groups may be at increased risk for complications or	11	Q. Another source of information is what you've
12	poor outcomes evolve over the years? Did you learn	12	been told by other physicians at meetings or informal
13	more as time went on on that subject?	13	3 conversations?
14	MR. SNELL: Objection, form. Go ahead.	14	A. Correct.
15	THE WITNESS: I will say that I	15	Q. Is there any other source of information
16	constantly learn about all the surgeries I do every	16	5 that I'm missing?
17	day. What has also changed is the environment in	17	A. Not that I can think of.
18	which I practice, to be 100% honest. As, I don't	18	Q. Your personal experience with the Prolift®
19	know, people may or may not know, there's a lot of ads	19	and the outcomes that you get in your group with
20	on TV about mesh. I go in to see my patients before	20	Dr. Lucente, how would you compare that those
21	surgery, and the TV is on and there's an ad saying,	21	outcomes with what you would expect to see in the
22	you know, 1-800 bad mesh. So to say that that hasn't	22	general community around the country?
23	impacted the way I practice would be untrue.	23	MR. SNELL: Objection, form. Go ahead.
24	BY MR. SLATER:	24	THE WITNESS: We tend to report a lot
25	Q. It's a good thing if the threat of	25	of our results. We tend to report, amongst other
	Pagi	e 119	Page 12
1	litigation will make doctors more cautious on who		things, our erosion rates. It's not uncommon at
2	they'll put mesh into; isn't that a good thing?		
3	MR. SNELL: Objection, form. Go ahead.	3	
4	THE WITNESS: I disagree with that		
5	statement.		
6	BY MR. SLATER:		
7	Q. Let me ask you this: You know that there are women who have suffered catastrophic injuries due		7 of well, let me ask you this: Do you believe that
8	ı v	3	
9	to complications from the Prolift®; you know that,	2	
10		10	•
11	MR. SNELL: Objection, form. Go ahead.	11	
12	THE WITCHESS: I don't have any personal	12	A. Are you talking about
	THE WITNESS: I don't have any personal		MD CMELL OL: 4' C C 1 1
	patients who have suffered catastrophic. I'm sure the	13	Ţ.
14	patients who have suffered catastrophic. I'm sure the people that are plaintiffs in this case would consider	14	THE WITNESS: specific communities
14 15	patients who have suffered catastrophic. I'm sure the people that are plaintiffs in this case would consider what has occurred to them as catastrophic.	14 15	THE WITNESS: specific communities or the whole every community combined other than
14 15 16	patients who have suffered catastrophic. I'm sure the people that are plaintiffs in this case would consider what has occurred to them as catastrophic. BY MR. SLATER:	14 15 16	THE WITNESS: specific communities or the whole every community combined other than ours?
14 15 16 17	patients who have suffered catastrophic. I'm sure the people that are plaintiffs in this case would consider what has occurred to them as catastrophic. BY MR. SLATER: Q. Let me ask you a question let me go	14 15 16	THE WITNESS: specific communities or the whole every community combined other than ours? BY MR. SLATER:
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14 15 16 17	patients who have suffered catastrophic. I'm sure the people that are plaintiffs in this case would consider what has occurred to them as catastrophic. BY MR. SLATER: Q. Let me ask you a question let me go through this a little bit with you. A. Sure.	14 15 16 17	THE WITNESS: specific communities or the whole every community combined other than ours? BY MR. SLATER: Q. That's what I'm asking about, the second part.
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	Do	ge 122		Daga 124
			a malair flagge that is a manufal sight have a second	Page 124
	1 than some people are finding.		1 pelvic floor, that is a potential risk because you can	
	2 BY MR. SLATER:		2 affect the nerves that go to the bladder and you could	
	Q. Do you feel that you have a solid		3 certainly either have a temporary or a more prolonged	
	4 understanding of what the actual complications rates		4 problem with urinary retention, but anything	
	5 and adverse events being seen out in the community		5 specifically related to the Prolift®, I don't know of	
	6 outside of your practice, do you feel a good		6 that.	
	7 understanding of that?		Q. When you read David Robinson's testimony	
	8 MR. SNELL: Objection, form.		8 regarding patients with urinary retention following	
	9 THE WITNESS: It's very hard because		9 Prolift® surgery, was that the first time you had been	
١.	0 it's very hard to get a denominator in terms of how	1		
	1 many are being done. You know, when I drafted the			
	2 time to rethink article, which I'm sure we'll talk		·	
	3 about, you know, I had attended the FDA open forum in,	1		
	4 I don't know, September 2011 and had gotten some	1	• 1	
	5 information from industry in terms of what a	1	•	
	6 denominator might have been during the time that the	1		
	7 reports came to the MAUDE database, and it actually	1	, 1	
	8 seemed that the rates of complications were actually,	1	• •	
	9 if you used that denominator in terms of how many had	1	5 1	
	0 been out there, sold to the public and how many have	2		
	1 been reported to the MAUDE database, they actually	2		
	2 seemed quite comparable.	2	•	
	Now, the problem with that is that not	2	•	
	4 everything gets reported to the MAUDE database. So	2		
2	5 that's the best educated answer I can give you.	2	5 urinary retention could result from the Prolift®	
	Pa	ige 123		Page 125
	Pa 1 BY MR. SLATER:		1 procedure? One way or another, do you know whether	Page 125
			1 procedure? One way or another, do you know whether 2 that was considered?	Page 125
	1 BY MR. SLATER:			Page 125
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	Post 120			
	Page 126			Page 128
	anyway, but if it's something that they didn't include	1		
2	on their first, you know, information but they assumed	2	yes.	
3	that it was something that people could infer from the	3	BY MR. SLATER:	
4	other information written there, I don't know that	4	Q. Has anybody ever told you that during the	
5	they'd have to go out of their way just because they	5	dissections of the sacrospinous ligament in connection	
6	found something out that they already knew was a	6	with the Prolift® procedure that the pelvic splanchnic	
7	potential risk.	7	nerves could be disrupted and that could cause or	
8	Like I said, urinary retention is a	8	contribute to urinary retention?	
9	risk any time you do pelvic reconstructive surgery.	9	A. Again, I don't think there is anything	
10	So if you say there's potential damage to the nerves	10	different about the dissection of the sacrospinous	
11	and the pelvis doing the Prolift®, well, then you can	11	ligament for Prolift® then, for instance, the	
12	sort of extrapolate that there is a risk of voiding	12	sacrospinous ligament suspension with suture.	
13	dysfunction afterwards.	13	Q. Well, you don't dissect tissue away from	
14	BY MR. SLATER:	14	both sides of the sacrospinous ligament when you do a	
15	Q. If Ethicon had reason to know that there	15	sacrospinous ligament fixation, correct?	
16	were aspects of the Prolift® procedure itself which	16	A. Both ways, what do you mean?	
17	could create a risk for urinary retention, that's	17	Q. Both sides.	
18	something you would expect Ethicon to warn about,	18	A. When you do a dissection for Prolift®, you	
19	meaning if there is something about the Prolift®	19	clear off the sacrospinous ligament.	
20	procedure itself which creates a particular risk for	20	Q. On both sides of it, correct?	
21	urinary retention?	21	A. I'm not aware of what you mean by "both	
22	A. Do you mean more so than any other	22	sides," but you clear off the ligament.	
23	reconstructive pelvic surgery?	23	Q. Okay. When you do a sacrospinous ligament	
24	Q. Yes.	24	fixation, the dissection of tissue from the sacral	
25	A. Yes, I think that would be a reasonable	25	spinous ligament is less extensive, correct?	
_	Page 127	+		Dogg 120
	Page 127		A. T. H.P. Malana	Page 129
1	thing that they would want to report.	1	A. I would disagree with that statement.	Page 129
2	thing that they would want to report. Q. If there was something about the Prolift®	2	Q. Do you know what the pelvic splanchnic	Page 129
3	thing that they would want to report. Q. If there was something about the Prolift® procedure that would in other words, would increase	2 3	Q. Do you know what the pelvic splanchnic nerves are?	Page 129
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	Page 130			Page 132
1	A. How are you defining "irritation of the	1	Q. Anything else you can remember?	
2	bladder"?	2	A. That's all I can remember right now.	
3	Q. Something that irritates the lining of the	3	Q. Let's talk about patients that you didn't	
4	bladder.	4	place the Prolift® in but came to you and you needed	
5	A. No.	5	to revise or remove mesh.	
6	MR. SNELL: Objection, form. Go ahead.	6	What were the reasons for those?	
7	THE WITNESS: No, because the Prolift®	7	A. It does become a little bit hard to remember	
8	mesh doesn't lie along the lining of the bladder. It	8	which ones were Prolift® versus which ones were some	
9	lies underneath the bladder.	9	other company's device, but I think all of them have	
10	BY MR. SLATER:	10	been mesh exposures.	
11	Q. Well, does the Prolift® mesh come into	11	Q. The 5 to 20 patients for which you've done	
12	contact with the bladder once it's placed?	12	mesh revisions and removals, was that just Prolift®,	
13	A. Yes, but not the bladder lining.	13	or does that include all mesh?	
14	Q. I was using lining and you're talking about	14	A. I think I was referring specifically to	
15	the inside of the bladder. I'm talking about the	15	Prolift® when I said that.	
16	outside.	16	Q. I thought you were too. I just want to make	
17	A. Okay.	17	sure.	
18	Q. So I used the wrong term.	18	A. Yeah, I think so, and would you like to know	
19	A. It lies next to the bladder. There's no	19	how many beyond that? Probably another 10 to 20 were	
20	evidence that I'm aware of that it irritates or	20	non-Prolift®.	
21	inflames the bladder by lying there.	21	Q. Have you ever spoken to any physicians who	
22	Q. Have you removed a revised Prolift® mesh	22	have removed or revised Prolift® mesh and the mesh of	
23	from women with complications?	23	the similar prolapse kits from more than 50 patients?	
24	A. Some.	24	A. Have I ever spoken to them personally?	
25	Q. How many?	25	Q. Yeah.	
	D 121	-	n n	122
	Page 131			Page 133
1	A. I would say somewhere in the range of 5 to	1	A. I may have spoken to them personally. I	Page 133
2	A. I would say somewhere in the range of 5 to 20.	1 2	A. I may have spoken to them personally. I don't know that we were speaking about that. I know	Page 133
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	Page 134			Page 136
1	Q. Are you able to point out, other than	1	BY MR. SLATER:	
2	Dr. Margolis' transcript and Dr. Elliott's transcript,	2	Q. I'll withdraw the question.	
3	which you said you believe you read completely, and	3	A. Okay.	
4	Dr. Lucente's you said you read	4	Q. When the fibrosis forms as a result of the	
5	A. 10%.	5	Prolift mesh in the woman's body, are there risks?	
6	Q. 10% can you give me any quantification of	6	A. Yes.	
7	how much of these other materials you reviewed?	7	Q. What are the risks?	
8	A. It would be something pretty close to a	8	A. I would say just like any other time	
9	guess. Let me say this, less than 20% of all of them.	9	fibrosis occurs, there's a risk for tenderness in the	
10	Q. In the list of materials there's literature,	10	area, and there is a risk of shortening of vaginal	
11	and on the second page of that there's a series of	11	length, and those can subsequently lead to functional	
12	articles towards the middle, where the first author in	12	outcomes.	
13	four straight is Klinge, K-l-i-n-g-e.	13	Q. When you say "functional outcomes," are you	
14	Do you see that?	14	talking about, for example, dyspareunia?	
15	A. I do.	15	A. Correct.	
16	Q. Do you know who that is?	16	Q. Are you talking about chronic pelvic pain?	
17	A. He's one of these names that I see in	17	A. Correct.	
18	regards to mesh, basic science regarding mesh.	18	Q. Are you familiar with the concept of	
19	Q. Anything else?	19	bridging fibrosis or scar plating?	
20	A. I don't know him personally. I don't even	20	A. I've heard of it, and I have a cursory	
21	know if it's a man or a woman, to be honest with you.	21	familiarity with it.	
22	Q. Have you made a point of studying the basic	22	Q. Do you have an understanding from your	
23	science with regard to polypropylene mesh and how it	23	review of materials in this case of what Ethicon's	
24	interacts within the woman's pelvis?	24	knowledge base has been with regard to bridging	
25	A. I certainly have tried to keep up on all the	25	fibrosis and scar plating?	
	Page 135			Page 137
1	Page 135 basic science, to the best of my ability, and I		MR. SNELL: Objection, form. Go ahead.	Page 137
	basic science, to the best of my ability, and I	1	·	Page 137
1 2 3	basic science, to the best of my ability, and I certainly want to apply that to my clinical experience		THE WITNESS: The only thing I would	Page 137
2 3	basic science, to the best of my ability, and I certainly want to apply that to my clinical experience with using mesh. Would I consider myself a basic	1 2	THE WITNESS: The only thing I would say is that I've been involved with some professional	Page 137
2	basic science, to the best of my ability, and I certainly want to apply that to my clinical experience	1 2 3	THE WITNESS: The only thing I would	Page 137
2 3 4	basic science, to the best of my ability, and I certainly want to apply that to my clinical experience with using mesh. Would I consider myself a basic science expert on histology of mesh? No.	1 2 3 4	THE WITNESS: The only thing I would say is that I've been involved with some professional education material that suggests, you know, the larger	Page 137
2 3 4 5	basic science, to the best of my ability, and I certainly want to apply that to my clinical experience with using mesh. Would I consider myself a basic science expert on histology of mesh? No. Q. When you talk about histology, you're	1 2 3 4 5	THE WITNESS: The only thing I would say is that I've been involved with some professional education material that suggests, you know, the larger the pore size, less chance of bridging fibrosis and	Page 137
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		Page 138			Page 140
	to the subject of bridging fibrosis and scar plating		1	OCCURS.	
2	and why the larger pores reduce that risk?		2	BY MR. SLATER:	
3	MR. SNELL: Objection, form.		3	Q. The larger pore being better?	
4	THE WITNESS: I don't recall from		4	A. Generally, if you're looking at microporous	
5	reading these particular documents of seeing a lot of		5	meshes, you are more concerned about fibrosis.	
6	information on that.		6	Q. Beyond that, do you have any other opinion	
7	BY MR. SLATER:		7	on that subject?	
8	Q. Was that a subject that you particularly		8	A. No, not at this time.	
9	looked at in doing your work in this case? Did you		9	Q. In all your interactions with Ethicon, did	
10	try to figure that out, did you look in the documents		10	anybody from Ethicon, whether it was formal or	
11	to try to find that information specifically?		11	informal, like it could be a professional education	
12	MR. SNELL: Objection, form.		12	event, it could be a document they provided to you or	
13	THE WITNESS: I did not.		13	it could just be a conversation, did anybody from the	
14	BY MR. SLATER:		14	company outside of your work as an expert in this	
15	Q. Do you have an understanding that if the		15	case, ever communicate to you what they knew about the	
16	pores of the mesh are 1 millimeter or greater in		16	significance of pore size?	
17	diameter once it's actually placed in the woman's body		17	A. Not that I recall.	
18	in actual use, that that reduces the risk of bridging		18	Q. Do you have an understanding of the	
19	fibrosis and scar plating?		19	mechanism that leads to what is termed contraction,	
20	MR. SNELL: Objection, form.		20	retraction and shrinkage?	
21	THE WITNESS: I'm sorry. I'm not		21	MR. SNELL: Objection, form. Go ahead.	
22	trying to be difficult. Just could you repeat the		22	THE WITNESS: I think I have a basic	
23	question?		23	clinical understanding of it, yes.	
	BY MR. SLATER:		24	BY MR. SLATER:	
25	Q. Sure. Are you familiar with any		25	Q. What is your understanding of what is	
	Q. Saler the year aminima with any		23	Q. What is your understanding or what is	
		Page 139			Page 141
1	significance to a 1 millimeter diameter of pore size		1	occurring and why?	
	significance to a 1 millimeter diameter of pore size once the mesh is actually placed with regard to		1 2	occurring and why? A. My understanding is that fibroblasts	
	•			·	
2	once the mesh is actually placed with regard to		2	A. My understanding is that fibroblasts	
2 3	once the mesh is actually placed with regard to whether or not that has any impact on bridging		2	A. My understanding is that fibroblasts invaginate into the spaces within a mesh, they lay	
2 3 4	once the mesh is actually placed with regard to whether or not that has any impact on bridging fibrosis or scar plating?		2 3 4	A. My understanding is that fibroblasts invaginate into the spaces within a mesh, they lay down fibrotic tissue like collagen, and that can cause	
2 3 4 5	once the mesh is actually placed with regard to whether or not that has any impact on bridging fibrosis or scar plating? A. I am not.		2 3 4 5	A. My understanding is that fibroblasts invaginate into the spaces within a mesh, they lay down fibrotic tissue like collagen, and that can cause scar type tissue that can contract.	
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	once the mesh is actually placed with regard to whether or not that has any impact on bridging fibrosis or scar plating? A. I am not. MR. SNELL: Objection, form. Go ahead. BY MR. SLATER: Q. Are you familiar at all with the information that Ethicon has in its own files with regard to whether or to what extent the one millimeter diameter of the pore sizes can have significance with regard to bridging fibrosis or scar plating? A. I recall, and I don't recall where, reading something about some people being concerned about 1 millimeter, thinking that was an odd number, but not specifically what impact that had on Gynecare's decision-making process. Q. Am I correct that you would not be forming any opinions or offering opinions with regard to the specific significance of the pore size with regard to bridging fibrosis and scar plating? Is that something you don't feel that you would be offering opinions on?		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. My understanding is that fibroblasts invaginate into the spaces within a mesh, they lay down fibrotic tissue like collagen, and that can cause scar type tissue that can contract. Q. Have you seen that with any mesh that you've actually explanted where you've actually looked for that? A. I have not seen a problem with mesh contraction personally. Q. Do you have an understanding of whether there were any factors with the Prolift® that would increase the risk of contraction, retraction, shrinkage occurring? A. Increase compared to what? Q. Is there anything about compared to well, I'll ask the question again. Do you have an opinion as to whether there's anything that one might do in implanting a Prolift®, placing it in the woman's body, that could increase the risk that the woman could end up with contraction, retraction or shrinkage of Prolift® mesh?	

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	Page 142			Page 144
1	is put in with too much tension on it, and it then is	1	Q. If I were to define tension as absolutely no	
2	referred to as a contracted mesh, when I don't think	2	tension on the mesh, it is loose and there's no	
3	that's really what happened.	3	tension on it, is that something that actually exists	
4	You know, I read a lot about this shrinkage,	4	with Prolift® placement?	
5	contraction, both in, you know, the FDA's warning and	5	A. Okay. Well, that's totally different	
6	in scientific literature. It's not something that I	6	MR. SNELL: Objection to form. Go	
7	have encountered in my vast experience using this	7	ahead.	
8	product and other products, specifically in relation	8	THE WITNESS: than the term tension	
9	to how it compares to other reconstructive pelvic	9	free. Tension free refers to a technique.	
10	surgeries.	10	BY MR. SLATER:	
11	Q. What is your understanding well,	11	Q. And that's how you define that term?	
12	rephrase.	12	A. Yes, that's how I would define that term.	
13	As you sit here now, are you saying that	13	Q. So when you refer to tension free, you're	
14	contraction, retraction, shrinkage doesn't occur, or	14	not talking about the outcome of the placement,	
15	are you saying that you just don't see it in your	15	meaning that there is no tension on it, correct?	
16	practice but you're not disputing that it occurs?	16	A. Correct. What I'm referring can I just	
17	A. The latter, I'm disputing that I think that	17	say what I think tension free is?	
18	mesh contraction is a major contributing factor to	18	Q. I'll ask the clean question. When you say	
19	adverse outcomes when using macroporous polypropylene	19	"tension free," what do you mean by that?	
20	monofilament meshes. You can certainly do an animal	20	A. What I mean by tension free is a term that	
21	study where you show that mesh contracts, you know, if	21	was coined when midurethral, minimally invasive	
22	you lay it in the belly of a rat or a rabbit. And I	22	synthetic slings were first developed. Specifically,	
23	certainly see that vaginal length often shortens after	23	I referred to the TVT® procedure, which stands for	
24	a Prolift® procedure, but my point was that I often	24	tension free vaginal tape.	
25	see that in native tissue repairs as well.	25	Prior to that slings were placed and they	
	see that in hair to tissue repairs as well		Those to that sings were placed and they	
	Page 143			Page 145
1	MR. SLATER: Move to strike I often see	1	were anchored in a specific point. So they were tied	Page 145
1 2	MR. SLATER: Move to strike I often see it in native tissue repairs.	1 2	over the rectus fascia. They were a bone anchor	Page 145
	MR. SLATER: Move to strike I often see it in native tissue repairs. BY MR. SLATER:		over the rectus fascia. They were a bone anchor was placed in the back of the pubic bone, something	Page 145
2	MR. SLATER: Move to strike I often see it in native tissue repairs. BY MR. SLATER: Q. What is your opinion as to why tension	2	over the rectus fascia. They were a bone anchor	Page 145
2 3	MR. SLATER: Move to strike I often see it in native tissue repairs. BY MR. SLATER: Q. What is your opinion as to why tensionwell, rephrase.	2 3	over the rectus fascia. They were a bone anchor was placed in the back of the pubic bone, something along those lines, where there was an actual fixation point.	Page 145
2 3 4	MR. SLATER: Move to strike I often see it in native tissue repairs. BY MR. SLATER: Q. What is your opinion as to why tension	2 3 4	over the rectus fascia. They were a bone anchor was placed in the back of the pubic bone, something along those lines, where there was an actual fixation	Page 145
2 3 4 5	MR. SLATER: Move to strike I often see it in native tissue repairs. BY MR. SLATER: Q. What is your opinion as to why tensionwell, rephrase.	2 3 4 5	over the rectus fascia. They were a bone anchor was placed in the back of the pubic bone, something along those lines, where there was an actual fixation point.	Page 145
2 3 4 5 6	MR. SLATER: Move to strike I often see it in native tissue repairs. BY MR. SLATER: Q. What is your opinion as to why tensionwell, rephrase. When you refer to "tension," what are you	2 3 4 5 6	over the rectus fascia. They were a bone anchor was placed in the back of the pubic bone, something along those lines, where there was an actual fixation point. When the tension free vaginal tape procedure	Page 145
2 3 4 5 6 7	MR. SLATER: Move to strike I often see it in native tissue repairs. BY MR. SLATER: Q. What is your opinion as to why tension well, rephrase. When you refer to "tension," what are you referring to?	2 3 4 5 6 7	over the rectus fascia. They were a bone anchor was placed in the back of the pubic bone, something along those lines, where there was an actual fixation point. When the tension free vaginal tape procedure came around, what was very unique about it was it	Page 145
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	•			Page 148
1	Q. So when you refer to tension free placement	1	A. It was in 2011. I don't recall exactly	
2	of the Prolift®, you're referring to the fact that	2		
3	when you place it, you don't actually anchor it to	3	Q. Did you start reviewing documents shortly	
4	another structure within the pelvis, correct?	4	after that?	
5	A. It's not anchored at a specific point,	5	A. I don't think shortly after. I think it was	
6	correct.	6	quite a few months after that.	
7	Q. Are there risks to using a suture to secure	7	Q. When did you first start reviewing documents	
8	the Prolift® at any point?	8	for your report in this case?	
9	MR. SNELL: Objection, form.	9	A. This would be my best estimation. It would	
10	MR. SLATER: I'll ask the question	10	be late 2011.	
11	again.	11	Q. How much time have you spent working on this	
12	MR. SNELL: I don't know what the	12	case?	
13	BY MR. SLATER:	13	A. I was just talking about this with my wife,	
14	Q. Are there any risks to using a suture to	14	because I'm very poor at keeping track of some of	
15	help place or support the Prolift® when it's placed in	15	these things.	
16	the body?	16	Q. Let me withdraw the question and ask it	
17	A. I just gave you a case of a patient that I	17		
18	sutured the mesh to the cervix using a braided suture,	18	Have you been invoicing for your time in	
19	and the suture itself caused granulation tissue within	19	this case and been getting paid?	
20	the patient's vagina.	20	A. I have.	
21	Q. Are there risks for creating Prolift®	21	Q. Because the defense normally would have	
			given me that disclosure, which they'll have to give	
22		22		
23	A. I guess I don't know what you mean by	23	me now later today or tomorrow or whatever, but do you	
	Prolift® complications.	24	know how much time you've invoiced for?	
25	Q. Meaning can that create tension on the mesh	25	A. I believe that I did an invoice for	
1				
	Page 147			Page 149
1	Page 147 that could lead to discomfort or complications?	1	somewhere in the range of 7 to \$8,000 this summer, and	Page 149
1 2		1 2	somewhere in the range of 7 to \$8,000 this summer, and I did an invoice for somewhere in the range of \$11,000	Page 149
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	Confidential - Subject to Stipula		
	Page 150		Page 152
1	A. Yes.	1	Q. And once you then saw some data indicating
2	Q. Another procedure that's available is either	2	that it was a safer alternative for sexually active
3	anterior or posterior colporrhaphy, correct?	3	women?
4	A. Correct.	4	MR. SNELL: Objection to form.
5	Q. Another procedure that can be performed is	5	THE WITNESS: I wouldn't say it was
6	sacrospinous ligament fixation, correct? A. Correct.	6	safer. I just say that we found better improvement in
7		′	sexual function afterwards. I still feel that Prolift® was safe.
8	Q. Another procedure that can be performed is uterosacral ligament fixation, correct?	8	BY MR. SLATER:
9	A. Correct.	9	
10	Q. There is another procedure that I've seen	10	Q. For sexually active women, you made a decision that Prolift+M® was a better choice than the
11	generally described as transvaginal repair. Are you	11	Prolift®, correct?
12	familiar with that term?	12	A. Correct.
13	A. No. Let me can I readdress that. I	13	Q. Do you know when it was that Ethicon
			first well, rephrase.
15	mean, transvaginal repair is just an approach to repairing a prolapse. If you do it transvaginally,		Do you have an understanding of the fact
16 17	it's transvaginal. It encompasses lots of different	16 17	that the Prolift+M® is the Prolift® but without the
	procedures, including anterior and posterior	18	Gynemesh® PS, instead Ultrapro® is used?
18	colporrhaphy, sacrospinous ligament fixation.	19	A. Yes.
	Q. The Prolift® is not one of the procedures	20	Q. Do you know when it was that Ethicon first
20	available to treat prolapse at this time, correct?	21	started to discuss the subject of using Ultrapro®
21	A. No. If you still have it on the shelf, you	22	rather than Gynemesh® PS in the Prolift® system?
23	could do it, but it's not being produced anymore, to	23	A. I do not know.
24	the best of my knowledge.	24	Q. Am I correct that you have no opinions as to
25	Q. Are you still doing Prolift®?	25	
23	Q. The you sain doing from to	23	whether of not Edition's Th windaw that:
	Page 151	1	Page 153
			rage 133
1	A. I haven't done one in a while.	1	As a physician treating women with prolapse,
1 2	A. I haven't done one in a while.Q. Did there come a point when you stopped	1 2	As a physician treating women with prolapse, including sexually active women, would you have wanted
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	Page 154			Page 156
1	you thought there were advantages to the Prolift+M®	1		rage 130
2	versus the Prolift®, right?	2	Q. You have no knowledge one way or the other	
3	A. Correct.	3		
4	Q. You would certainly as an expert in this	4	A. No.	
5	litigation would agree with me that when people within	5	Q. One of the things that can occur once a	
6	Ethicon whose job it was to help to develop products	6	Prolift® is in a woman's body is that she can get	
7	like the Prolift® or alternatives, once they started	7		
8	to realize help the use of Ultrapro® could be better	8	A. Correct.	
9	and could be better for sexually active women or	9	Q. One of the things that can occur when a	
10	reduce complications, you would expect that Ethicon	10	woman has recurrent mesh erosions well, rephrase.	
11	would have moved as quickly as possible to look into	11	One of the things that can occur once a	
12	that so that if that turned out to be true, that could	12	Prolift® is placed in a woman's body is the woman can	
13	be made available as soon as possible, right?	13	begin to feel pain, correct?	
14	MR. SNELL: Objection, form.	14	A. Correct.	
15	THE WITNESS: I guess it depends on	15	Q. And one of the things that physicians do	
16	what evidence they had. If they just had a hunch,	16	when a woman is complaining of pain after a Prolift®	
17	then I wouldn't necessarily fault them for not doing	17	is placed is to do exploratory surgery to try to see	
18	it. It all depends on what evidence they had.	18	if the mesh is causing the pain; that's one of the	
19	BY MR. SLATER:	19	things surgeons do, correct?	
20	Q. You have no knowledge one way or the other	20	A. That would be a very aggressive first step	
21	as to when anybody in the research and development arm	21		
22	of Ethicon first started to advocate to utilize	22	Q. You're aware that there are surgeons who	
23	Ultrapro® rather than Gynemesh® PS in the Prolift®	23	treat women who are complaining of pain with the	
24	system?	24	Prolift® who after trying to conservatively treat the	
25	A. To advocate to whom?	25	women for a period of time will do an exploratory	
	Page 155			Page 157
_	0 04 4 141 4		1	
1	Q. Other people within the company.	1		
2	A. No, no idea. I never worked at Ethicon.	2	of the pain, correct?	
2 3	A. No, no idea. I never worked at Ethicon.Q. And you saw no documents in that regard?	2	of the pain, correct? A. I'm aware that they do exploratory surgery	
2 3 4	A. No, no idea. I never worked at Ethicon.Q. And you saw no documents in that regard?A. I don't recall seeing documents that talked	2 3 4	of the pain, correct? A. I'm aware that they do exploratory surgery for that. I don't know if it's for that purpose, but,	
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	Page 158		Page 16
1	MR. SNELL: Objection, form.		of the Prolift® being in her body because that's what
2	THE WITNESS: What I'd say is that all		the surgeon is investigating, correct?
3	those repeat surgeries, that might cause the patient	3	A. That's where you and I
4	to continue to have pain, but that doesn't mean that	4	MR. SNELL: Objection to form. Go
5	the Prolift® was causing the pain in the first place.	5	ahead.
6	BY MR. SLATER:	6	THE WITNESS: That's where you and I
7	Q. Well, if a woman has a Prolift® in her body	7	have a disagreement. You're saying because the
8	and the surgeon rephrase.	8	Prolift® was left in the patient. I'm saying that the
9	Let's take a woman who has a Prolift®	9	surgery itself, okay, having nothing to do with the
10	placed.	10	mesh itself, the surgery just isn't you throw mesh at
11	A. Yeah.	11	the patient. The surgery is you dissect, you ligate
12	Q. She is complaining of pain after the	12	things, you know, you stop bleeders, you dissect, and
13	Prolift®. The surgeon surmises after he's treated her	13	the pain could be caused by that process, not just
14	for a period of time that the Prolift® is the cause	14	from the mesh being left in the patient.
15	and decides to operate to try to determine whether the	15	Does that make sense?
16	Prolift® is the cause and remove some of the mesh,	16	BY MR. SLATER:
17	take that scenario, okay?	17	Q. The Prolift® procedure that was performed
18	A. Yes.	18	from incision to closing can lead to the pain, as well
19	Q. That surgery took place as a result of the	19	as the mesh itself can lead to the pain, correct?
20	Prolift® being put in the woman's body because but for	20	MR. SNELL: Objection.
21	the Prolift®, the surgeon is not operating to try to	21	BY MR. SLATER:
22	investigate whether the Prolift® is causing pain,	22	Q. Is that what you're saying?
	correct?		
23		23	MR. SNELL: Objection, form.
24	MR. SNELL: Objection, form.	24	THE WITNESS: No, I'm saying that the
25	THE WITNESS: No, I would disagree with	25	surgery itself can lead to pain.
	Page 159		Page 16
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-	that. He's thinking that the surgery that he	1	MR. SLATER. We'll come back to this.
2	performed caused the pain.	2	THE VIDEOGRAPHER: Going off the
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		Page 162			Page 164
1	is the difference?		1	BY MR. SLATER:	
2	A. Generally, the major difference is that she		2	Q. Looking at Exhibit 899 in the third	
3	had prolapse of her pelvic organs before and		3	paragraph, Piet Hinoul is talking about erosion rates	
4	afterwards she doesn't. In addition, she has		4	in certain studies with regard to the Prolift®.	
5	polypropylene mesh in the spaces between the vagina		5	Do you see that?	
6	and the bladder in the form of the anterior and		6	A. Yes.	
7	between the vagina and the rectum in the form of the		7	Q. And he points out that Elmer and Altman had	
8	posterior.		8	11% erosion in one of their trials.	
9	Q. For lack of a better word, once the Prolift®		9	You see that?	
10	is placed, is the actual engineering or architecture		10	A. Yes.	
11	of the pelvic floor different than what it was before		11	Q. And they say that the Withagen, the Dutch	
12	the Prolift® mesh was placed?		12	prospective trial had a 10% erosion rate?	
13	MR. SNELL: Objection, form.		13	A. Correct.	
14	THE WITNESS: Yeah, there is no longer		14	Q. And then he says, "Who believes	
15	prolapse of the pelvic organs.		15	Mr. Lucente's group when Van Raalte publishes that	
16	BY MR. SLATER:		16	they have no erosions? Nobody!"	
17	Q. And in terms of the pelvic floor itself, in		17	You see that?	
18	terms of what it's made up of, is that different now		18	A. I see that.	
19	that the Prolift® mesh has been placed?		19	Q. Is this the first time you're being made	
20	A. Yes. Women are not born with polypropylene		20	aware that Piet Hinoul documented that, from his	
21	meshes in their body.		21	perspective, nobody believes the data that your group	
22	Q. So the condition of the pelvic floor before		22	was reporting with regard to erosion rates?	
23	the Prolift® is placed is different from what the		23	MR. SNELL: Objection, form.	
24	condition is once the Prolift® has been placed; is		24	THE WITNESS: No. I've recently seen	
	that correct?		25	this, this e-mail.	
23	that correct.		23	uns, uns e man.	
		Page 163			Page 165
1	A. From before to after, it's different, yes.	Page 163	1	BY MR. SLATER:	Page 165
1 2	A. From before to after, it's different, yes.Q. I'm going to show you a document that was	Page 163	1 2	BY MR. SLATER: Q. Did you ever discuss it with Piet Hinoul?	Page 165
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	D 166			D 100
	Page 166			Page 168
	erosions, and we've published studies or at least	1	Q. Do you have any opinion one way or the other	
2	presented our own research that shows that, yes, we	2		
3	get erosions. It just so happened in this one we had	3	A. No, I do not.	
4	none.	4	Q. Did you read Dr. Lucente's deposition	
5	Q. Are the results from your group	5	testimony on that subject?	
6	representative of the results that physicians across	6	A. I don't think I did.	
7	the board would get, or would you agree that the data	7	Q. If Dr. Lucente said something to the effect	
8	that you have compiled with regard to your results of	8	of your group has a much higher skill level and most	
9	your patients is better than what most people can	9	erosions are due to the skill level of the surgeons,	
10	obtain?	10	which explains why your group has such lower rates,	
11	MR. SNELL: Objection, form, go ahead.	11	would you agree with that?	
12	THE WITNESS: Again, it's hard for me	12	MR. SNELL: Objection, form.	
13	to speak to what most people what results they get.	13	THE WITNESS: I wouldn't be surprised	
14	I can only look at what other people have published.	14		
15	Certainly, when I talk to people at meetings, they	15	BY MR. SLATER:	
16	seem to say that, you know, their erosion rates for	16	Q. Would you agree with it?	
17	whatever transvaginal mesh procedure they're doing	17	A. No.	
18	tends to be closer to 3 to 10%. But, again, when you	18	Q. What are the factors that lead to erosion of	
19	look at our larger series, you know, we quote 3%	19	Prolift® mesh?	
20	erosion rate.	20	A. And let me just is it okay if I qualify	
21	BY MR. SLATER:	21		
22	Q. Do you believe that the skill level of you	22	Q. Sure.	
23	and Dr. Lucente and the surgeons in your group is the	23	A. I think that technique used in doing the	
24	reason why your erosion rates are lower than the	24	surgery definitely affects the outcome, but whether I	
25	erosion rates of other published and reported studies?	25	can say ours are that we have greater skill than	
	Page 167	+-		Page 169
				1 age 109
1	A. You know, I've talked to people I	1	all the other surgeons out there, I just I don't	1 age 109
1 2			all the other surgeons out there, I just I don't feel comfortable expressing that opinion.	1 age 109
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2 3	A. You know, I've talked to people I specifically know, thinking about people who practice	1 2	feel comfortable expressing that opinion.	1 age 109
2 3 4	A. You know, I've talked to people I specifically know, thinking about people who practice in New Jersey, who often do different type of mesh	1 2 3	feel comfortable expressing that opinion. Q. Well, do you have an explanation for why the	rage 109
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	Page 170			Page 172
1	A. I don't.	1	an exposure of a Prolift® mesh, it is along the	
2	Q. Okay.	2	midline, so meaning it is where the incision was, and	
3	A. I just know who they had to re-operate on.	3	so it's probably related to the incision line not	
4	But, again, sitting here without all the papers in	4	healing properly over the mesh.	
5	front of me, I think there are other people that have	5	The second place where I sometimes see them	
6	published erosion rates around 5%. So is the	6	is in relation to where the mesh might be anchored in	
7	difference between 5 and 3% significant, I don't know.	7	place with a suture. So it could be related to the	
8	That's up to the person who is looking at that.	8	inflammatory process at those locations.	
9	But it's possible that it's related to our	9	Q. And that's based on your own experience?	
10	technique for hydro dissection. It's possible that	10	A. That is based on my experience in talking to	
11	it's related to full thickness incisions. It's	11	other people, other colleagues.	
12	possible that it's related to the fact that people in	12	Q. Are you aware of any other reasons why	
13	Southeastern Pennsylvania, you know, have healthier	13	erosion into the vagina can occur?	
14	vaginal tissues. I don't know for sure. It's	14	A. Well, I've certainly read the depositions of	
15	different women.	15	the expert witnesses on the plaintiff's side that	
16	Q. What are the factors that lead to erosion of	16	suggest that all erosions are related to infection and	
17	Prolift® mesh?	17	that, basically, you can't place a mesh to the vagina	
18	A. I don't know how to answer the question of	18	without it being infected.	
19	what are factors. Do you mean what are risk factors?	19	Q. Do you think there's any validity to the	
20	Looking into someone before they have surgery, what	20	viewpoint that infection of Prolift® mesh can cause	
21	their risk factor is going to be; is that what you	21	erosion through the vaginal wall?	
22	mean?	22	A. I don't think there is much validity to	
23	Q. This is my question: In your opinion, why	23	that, no. I think that it's probably that once an	
24	is it that Prolift® erosions occur? What are the	24	erosion occurs, if you were to culture that, you would	
	reasons why it occurs?	25	see bacteria because it's exposed to the vagina, where	
23	reasons why it occurs.	23	see bacteria because it's exposed to the vagina, where	
	Page 171			Page 173
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1 2		1 2	there's ton of bacteria naturally. Q. Did you read what Axel Arnaud said about	Page 173
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		Page 174			Page 176
1	BY MR. SLATER:		1	THE WITNESS: I do not recall.	
2	Q. Let me show you a document marked as Exhibit		2	BY MR. SLATER:	
3	1217 at a prior deposition. It's an article that you		3	Q. I'll give you an exhibit we've marked as	
4	were the first listed author on.		4	895, which is a manuscript titled "Short-Term Results	
5	A. Yes.		5	of the Prolift® Procedure in 349 Patients Used in the	
6	Q. And what I'd like to do is ask you to turn		6	Treatment of Pelvic Organ Prolapse."	
7	to Page 276 of the article, which is titled "Vaginal		7	A. Sorry, I got two.	
8	Hysterectomy at the time of Transvaginal Mesh		8	Yes, I see it. I have it.	
9	Placement," which published in 2010, correct?		9	Q. And you're one of the authors of that	
10	A. Correct.		10	article, correct?	
11	Q. At the bottom of the left-hand column under		11	A. I am.	
12	the discussion section there's a sentence that reads		12	Q. And as with the prior article, co-authors	
13	as follows: "In fact, even 2 or 3 years of follow-up		13	include Heather van Raalte, Robin Haff, Vincent	
14	without erosion does not guarantee a future free from		14	Lucente, correct?	
15	erosion; there is no safe time from erosion when		15	A. Correct.	
16	permanent materials are used."		16	Q. All members of at the time the same your	
17	Do you see that statement?		17	group in Pennsylvania?	
18	A. I do.		18	A. I don't see a date on this, but, certainly,	
19	Q. And that's a statement you co-authored,		19	Heather was with us for three years, Dr. van Raalte.	
20	correct?		20	Q. And then she went to another practice,	
21	A. Correct.		21	correct?	
22	Q. And you believe it to be true, correct?		22	A. Correct.	
23	A. Correct.		23	Q. Now, do you know when this was well,	
24	Q. And you believe it to be true with regard to			rephrase.	
	the Prolift®, correct?		25	Was this ever published?	
	,			1	
			1		
		Page 175			Page 177
1	A. Correct.	Page 175	1	A. This manuscript, to the best of my	Page 177
1 2	A. Correct.Q. To your knowledge, was Ethicon aware of	Page 175	1 2	A. This manuscript, to the best of my knowledge, was never published.	Page 177
		Page 175		•	Page 177
2	Q. To your knowledge, was Ethicon aware of	Page 175	2	knowledge, was never published.	Page 177
2 3	Q. To your knowledge, was Ethicon aware of that?	Page 175	2	knowledge, was never published. Q. Why not?	Page 177
2 3 4 5	Q. To your knowledge, was Ethicon aware of that?A. To my knowledge, any person who has any	Page 175	2 3 4	knowledge, was never published. Q. Why not? A. Because it takes a lot of work to get a	Page 177
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2 3 4 5 6	Q. To your knowledge, was Ethicon aware of that? A. To my knowledge, any person who has any basic understanding of biology, life, if you put a permanent material in someone, you never know what	Page 1/5	2 3 4 5 6	knowledge, was never published. Q. Why not? A. Because it takes a lot of work to get a manuscript published, and my guess is that Heather excuse me Dr. van Raalte started her practice, was	Page 177
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	Page 178			Page 180
1	any ongoing studies when you were involved in doing a	1	dyspareunia symptoms resolved by the three or	
2	study?	2	six-month follow-up visit, yes, I see that.	
3	A. Did I ever any study whatsoever, yes, I'm	3	Q. What do you attribute that to, the fact that	
4	sure I did.	4	dyspareunia symptoms would resolve in some patients	
5	Q. There's nothing that comes to mind?	5	but not in others after these procedures?	
6	A. No.	6	A. I mean, it most likely is related to the	
7	Q. This indicates in the results section of the	7	effects of inflammation and scar tissue post surgery	
8	abstract postoperative voiding dysfunction in 3.4% of	8	that often will, for lack of a better term, cool down	
9	the patients.	9	over time.	
10	Do you see that?	10	Q. When you say it's due to the effects of	
11	A. I do.	11	inflammation and scar tissue, what are you	
12	Q. And this was 349 patients total that had	12	specifically referring to?	
13	·	13	A. I'm not specifically referring to anything.	
14	A. Correct.	14	Q. Well, I asked you why well, let me ask	
15	Q. According to the paper, these were performed	15	you the question more generally. Why would in some	
16	between February 2005 and May 2006, that's on Page 5.	16	patients who have Prolift® and report dyspareunia some	
17	A. Okay.	17	would resolve and in some it would be a persistent	
18	Q. When you refer in this article to voiding	18	condition?	
19		19	MR. SNELL: Objection, form. Hold on.	
20	A. Difficulty emptying of the bladder.	20	THE WITNESS: I don't know exactly.	
	Q. Does that include urinary retention?	21	MR. SNELL: Go ahead. Withdraw the	
21	A. Partial urinary retention, I would think. I			
22	•	22	objection.	
23	don't think anybody is completely complete	23	THE WITNESS: I don't know exactly why	
24	retention, and can I continue on that? I mean, we	24	it would be. You know, I know that around this time	
25	didn't just do Prolift® in these cases, just so you're	25	we had done I'm not sure if it was this study or	
	Page 179			Page 181
1	Page 179 aware. These also included patients who had slings.	1	another study that suggests that when we looked at	Page 181
1 2		1 2	another study that suggests that when we looked at people that had more chronic pain postoperatively, the	Page 181
	aware. These also included patients who had slings.		, , , ,	Page 181
2	aware. These also included patients who had slings. Q. Is there a higher risk for voiding	2	people that had more chronic pain postoperatively, the	Page 181
2 3	aware. These also included patients who had slings. Q. Is there a higher risk for voiding dysfunction when a Prolift® is done along with a SUI	3	people that had more chronic pain postoperatively, the majority of those patients had had prior surgery or	Page 181
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	Confidential - Subject to Stipu Page 19		on and order of confidential:	Page 184
1	general. Sometimes it can be related to shortening of	82 1	Q. And then as to the women that do have	rage 184
2	the vagina, deviation of the axis of the vagina.	2	intervention, you're saying those would be resolved?	
	Q. When a woman has native tissue repair and		A. They would have a slightly higher chance of	
3	reports dyspareunia, in most cases it will resolve on	3		
4	its own, correct?	5	Q. Is there any data or studies you can point	
5	A. I would not agree with that.		to for these percentages?	
6	· ·	6	A. I can't, no.	
7	Q. Let me ask you this: When a woman has native tissue repair and develops dyspareunia, are	7	Q. Now, when a woman has a Prolift® placed in	
8		8	•	
9	there treatments that are used to try to treat that? A. Of course there are.	9	her body and has dyspareunia following that, complains	
.0		10	of dyspareunia, what is it about the Prolift®	
.1	Q. What?	11	procedure, the mesh, the Prolift® instruments, what	
.2	A. Sometimes re-operation, sometimes physical	12	about those things can lead to dyspareunia?	
.3	therapy, sometimes vaginal estrogen, sometimes vaginal	13	MR. SNELL: Objection, form.	
4	dilators.	14	THE WITNESS: I think the same things	
.5	Q. Do you have an opinion as to an overall	15	that can lead to dyspareunia after a native tissue	
.6	percentage of women who have native tissue repair and	16	repair are the same things that can lead to	
.7	develop dyspareunia as to how many of them either	17	dyspareunia after the Prolift®, with the exception of	
8	it goes away on its own or it's treated successfully,	18	you can't get dyspareunia related to a mesh erosion if	
.9	as opposed to those that where it doesn't?	19	you don't put mesh in someone.	
0	A. I haven't seen any. I can't recall seeing	20	BY MR. SLATER:	
1	any literature on that point.	21	Q. Let me ask you this question: With regard	
2	Q. So there's no percentages that you can offer	22	to the Prolift® mesh, the instruments and the Prolift®	
3	me, as you sit here now?	23	procedure to place the mesh, what about those things	
4	A. In terms of how much will resolve	24	that are particular to the Prolift® itself that can	
25	spontaneously?	25	cause or contribute to dyspareunia?	
	Page 18	83		Page 18
1	Q. Or through treatment as opposed to if anyone	1	MR. SNELL: Objection, form.	
2	won't.	2	THE WITNESS: I think it's I guess	
3	A. No, I certainly can't quote you anything.	3	I'm having trouble answering that question. Someone	
4	If you wanted me to give you my expert opinion on what	4	can have dyspareunia for lots of reasons after	
5	might, I certainly could.	5	surgery. I don't know that there's anything unique to	
6	Q. Well, I want to know if you have an opinion.	6	Prolift® that can cause it.	
7	I don't want you to just surmise or, you know, guess	7	BY MR. SLATER:	
8	at something. If you have a reasonable an opinion	8	Q. Let me try to explain to you what I'm trying	
9	to a reasonable degree of medical probability, then	9	to get at.	
.0	that's fine, but if it's not, you can tell me I would	10	A. Okay.	
1	just be guessing or speculating.	11	Q. What about the Prolift® procedure,	
.2	A. Well, let me put it this way, because it	12	everything that needs to be done to place the Prolift®	
. 3	depends on when you define when the dyspareunia is	13	from start to finish, the Prolift® mesh itself, which	
.4	starting. So if someone has dyspareunia the very	14	is being placed in the body and remains in the body,	
.5	first time they have sex after surgery, what's the	15	and the instruments that are used during the procedure	
6	chance of that resolving, that's pretty high. I would	16	to place the Prolift®, what about those specific	
7	say, you know, it's very likely that more than half of	17	things can lead to dyspareunia?	
.8	those people will have resolution of their symptoms.	18	MR. SNELL: Objection, form, asked and	
.9	If you're talking about someone who has	19	answered.	
20	dyspareunia for the first six months after their	20	THE WITNESS: Could I have a pen just	
-	native tissue repair and then some percentage of those	21	so because there's lots of parts to that question.	
1	1		• •	
	will resolve after six months of having it. I would	22	I want to answer correctly in the future. Thank you.	
2	will resolve after six months of having it, I would say that there is a good likelihood that without		I want to answer correctly in the future. Thank you. So, certainly, making an incision,	
22 23 24	say that there is a good likelihood that without	23	So, certainly, making an incision,	
2	· ·			

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	Page 186			Page 188
1	dyspareunia.	1	Q. What I'm saying is what about my question	
2	Laying, again, as I referred to	2	is this: What about the Prolift® procedure, the	
3	earlier, a mesh under that's too tightly placed, again	3	Prolift® mesh, the Prolift® instruments can cause a	
4	to differentiate from what tension free means, I think	4	woman to suffer from dyspareunia?	
5	that can lead to dyspareunia.	5	A. Okay. I think I answered that question.	
6	I think postoperative inflammation can	6	MR. SNELL: Objection, form. Go ahead.	
7	lead to dyspareunia.	7	BY MR. SLATER:	
8	BY MR. SLATER:	8	Q. And the answer was the incision that's made	
9	Q. Anything else specific to the Prolift®, as I	9	the closure of the incision, laying the mesh and the	
10	defined it?	10	mesh then being too tight?	
11	A. I don't think you asked specific to	11	A. Laying the mesh too tightly, yes.	
12	Prolift®. You just said with Prolift®.	12	Q. And postoperative inflammation?	
13	Q. Well, I did. The question is this: What is	13	A. Correct.	
14	it about the Prolift® procedure, the Prolift® mesh,	14	Q. That postoperative inflammation can be due	
15	the Prolift® instruments, what is it about which	15	to the mesh itself, correct?	
16	I'm calling the Prolift® system, what is it about	16	A. I guess so because there's inflammation when	
17	that, putting that into the body and then it being in	17	you put a mesh in. You also have inflammation when	
18	the body that can lead to a woman suffering from	18	you don't put in a mesh after surgery, but, yes, you	
19	dyspareunia?	19	certainly have it in relation to the mesh.	
20	MR. SNELL: Objection, form.	20	Q. If the mesh well, rephrase.	
21	THE WITNESS: But when you say specific	21	Can the fibrosis that forms as a result of	
22	to that, that implies that making an incision is	22	the mesh being in the body cause or contribute to	
23	because that's part of the Prolift® procedure, okay.	23	dyspareunia?	
24	BY MR. SLATER:	24	A. Can the mesh, the fibrosis and the	
25	Q. So that's part of my question then, because	25	inflammation that occurs, can that lead to	
-	D 107			D 100
-	Page 187			Page 189
1	to put a Prolift® in, you have to perform the Prolift®	1	• •	Page 189
2	to put a Prolift® in, you have to perform the Prolift® procedure so that's part of it.	2	Q. Yes.	Page 189
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			on and order of confidentiali	
	Page 190			Page 192
1	and I sewed that shut or I trimmed tissue well, I	1	Q. When a woman has multiple surgeries	
2	don't do that in a Prolift® procedure, but if I were	2	following a Prolift® procedure in an effort to treat	
3	doing a native tissue repair and I did that and it	3	complications that she's suffering from, can the	
4	shortened it, then that I guess what I'm trying to	4	multiple procedures lead to the development of pelvic	
5	get at is is that I think whatever anybody is calling	5	floor myalgia?	
6	contraction of the mesh would lead to shortening of	6	A. Yes, although one would assume that if she's	
7	the vagina, and that's what would lead to the pain,	7	having those procedures in the first place, she had	
8	not that the area around the mesh was contracted.	8	pelvic floor myalgia. Meaning you're saying she had	
9	MR. SLATER: Just I'll move to strike	9	surgery because she had pelvic pain, and, you know,	
10	as referred to other procedures.	10	it's a fine line when someone can't say, well, my	
11	BY MR. SLATER:	11	muscle hurts, but my vaginal lining doesn't hurt.	
12	Q. Are you aware that there are people within	12	Q. Well, a surgeon can evaluate a woman on the	
13	Ethicon who believe that contraction of Prolift® mesh	13	exam, find no signs of myalgia, operate to treat	
14	can cause dyspareunia?	14	whatever pain the patient is complaining of, and then	
15	A. I don't have any recollection of reading	15	later the patient can begin to display clinical	
16	that or anyone saying that to me.	16	symptoms and signs of myalgia, correct?	
17	Q. Do you believe that contraction of Prolift®	17	MR. SNELL: Objection, form.	
18	mesh can cause or contribute to dyspareunia?	18	BY MR. SLATER:	
19	A. I think that, again, the mesh doesn't	19	Q. You're not saying that every woman with a	
20	contract, the tissues around it contract, and that can	20	complaint of pelvic pain it's due to myalgia?	
21	lead to shortening of the vagina, which could lead to	21	A. I'm saying that	
22	dyspareunia.	22	MR. SNELL: Note my objection to both	
23	Q. Can the Prolift® procedure or the mesh	23	questions.	
24	remaining within the body after the procedure which	24	THE WITNESS: I'm saying it's often	
25	has been placed, can that lead to irritation of nerves	25	very hard to determine why someone has pelvic pain.	
	-			
	Page 191			Page 193
1	which can cause dyspareunia?	1	There is no test that you can do in someone that has	Page 193
1 2	which can cause dyspareunia? MR. SNELL: Objection, form.	1 2	pelvic pain that I'm aware of that says definitively	Page 193
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	Page 194	Т.		Page 196
1	A. Yes.	1	are likely to be upset with you, okay, and you want to	Page 196
2	Q. A little further down you state in this	2	make sure that you've not done something that might	
3	article along with your co-authors rephrase.	3	expose you to medical-legal risk.	
4	On Page 10 of this article about halfway	4	Q. That's the point that's the reason why	
5	down, there is a sentence that states, "Based on our	5	you and your co-authors wrote that there?	
١.	outcomes, patients with chronic pain conditions,	6	A. I'm saying that's why I would agree with	
6	pre-existing pelvic pain and a history of pelvic	7	this statement.	
7	surgery should be carefully counseled about the	8	Q. Do you agree with the proposition stated	
8	potential risk of postoperative dyspareunia and		here that with these types of patients with chronic	
9	avoidance of mesh use should be considered."	9	pain, pre-existing pelvic pain or a history of pelvic	
10	Do you see where I'm reading?	10	surgery, that because they have more risk of	
12	A. I do.	12	postoperative dyspareunia, avoidance of using mesh	
13	Q. And you believed that to be a true statement	13	should be considered?	
14	when this article was written?	14	MR. SNELL: Objection, form.	
15	A. Well, let me answer that question this way:	15	THE WITNESS: I think that's what I'm	
16	I wasn't the only author on this paper. I doubt I	16	saying, yes.	
17	wrote that sentence. I certainly think that it is a	17	BY MR. SLATER:	
18	true statement in that it's suggesting that patients	18	Q. The way that this reads it's indicating that	
19	who have these chronic pain syndromes before the	19	with these patients, you should consider avoiding the	
20	Prolift® surgery are more likely to have chronic pain	20	use of mesh. It doesn't say you should try to find a	
21	afterwards. Whether or not you should, therefore,	21	way not to operate on them at all. That's a true	
22	avoid the use of mesh, I think, in general, you should	22	statement, correct?	
23	try and do everything you can not to operate on those	23	A. That's a true statement.	
24	patients in the first place. Do I think that actually	24	MR. SNELL: Objection to form.	
25	putting mesh in them is going to increase that risk?	25	THE WITNESS: Because this is a paper	
23		23	THE WITTESS. Because and is a paper	
	Page 195			Page 197
1	Not necessarily. Do I think it's going to expose you	1		
1 2	to more liability because they can say it's because of	1 2	about Prolift®. It's not a paper about generally operating on patients with prolapse.	
	to more liability because they can say it's because of that particular product being in there? Yes.			
2	to more liability because they can say it's because of that particular product being in there? Yes. Q. In this statement in the article which you	2	operating on patients with prolapse. MR. SLATER: Move to strike from because forward.	
2 3	to more liability because they can say it's because of that particular product being in there? Yes. Q. In this statement in the article which you co-authored	2 3	operating on patients with prolapse. MR. SLATER: Move to strike from because forward. MR. SNELL: Denied.	
2 3 4 5 6	to more liability because they can say it's because of that particular product being in there? Yes. Q. In this statement in the article which you co-authored A. Yes.	2 3 4 5 6	operating on patients with prolapse. MR. SLATER: Move to strike from because forward. MR. SNELL: Denied. BY MR. SLATER:	
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		Page 198			Page 200
	contonos	1 age 170	1	putting in the permanent Prolift® just because of her	1 age 200
	A. Similarly, younger, sexually active patients		1	life expectancy and the fact that she's sexually	
2			2		
3	should be counseled regarding the potential for		3	active as compared to someone who may be older and not	
4	dyspareunia following mesh placement and alternative		4	sexually active; is that my understanding?	
5	treatment should be discussed. I would agree that in		5	MR. SNELL: Objection, form.	
6	my practice, I am somewhat leery of doing a Prolift®		6	THE WITNESS: No. What I'm saying is	
7	procedure in a very young patient.		7	that if there's an alternative to not using mesh in	
8	Q. What do you define as a very young patient?		8	someone that you're concerned about long term	
9	A. I would say someone in their 30s, early 40s.		9	sequelae, you might want to try that first, not in all	
10	Q. And you would be leery of that why?		10	cases, but certainly in some cases.	
11	A. Again, to my point that well, here's the		11	BY MR. SLATER:	
12	difficulty with treating young, sexually active		12	Q. Well, you stated in this article that you	
13	patients who have prolapse, okay, it's a fine line		13	should counsel, you're recommending to other	
14	between durability and functionality. Procedures, in		14	physicians, you should counsel younger, sexually	
15	my opinion, that tend to you have to balance		15	active patients regarding the potential for	
16	between the function of the vagina and durability, and		16	dyspareunia following mesh placement and alternative	
17	that's why we use that's why there's a debate about		17	treatment options should be discussed, right?	
18	mesh in general, okay. Most people use mesh use it		18	A. Correct.	
19	because they want to improve the durability of the		19	Q. And that's because of the particular risk	
20	repairs, okay. You have to balance that with the risk		20	that a woman who is younger and sexually active would	
21	of any change in functionality, like pain from an		21	face if complications were to occur with the Prolift®	
22	erosion, okay.		22	as well as the long-term risk, correct?	
23	And it's a conundrum of, well, for those		23	MR. SNELL: Objection, form.	
24	very same reasons you'd want to use mesh in a young		24	THE WITNESS: I think I am mostly	
25	patient, whether it be vaginally or abdominally, you		25	referring to the long-term risk.	
		Page 100			Page 201
1	have to also think about the rescons why you might not	Page 199	1	BV MD SI ATED.	Page 201
	have to also think about the reasons why you might not	Page 199	1	BY MR. SLATER: O The concern for the consequences that could	Page 201
2	want to, because you can't get an erosion of mesh if	Page 199	2	Q. The concern for the consequences that could	Page 201
3	want to, because you can't get an erosion of mesh if you don't use mesh.	Page 199	2	Q. The concern for the consequences that could potentially occur for younger, sexually active woman	Page 201
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			on and order or confractional	D 204
	Page 202			Page 204
1	specifically referred to myself to answer the first	1	because it's often a we look at relative risk many	
2	part of your question.	2	times in medicine.	
3	BY MR. SLATER:	3	Q. Well, coming back to my question, you noted	
4	Q. So are you saying you are not able to tell	4	the fact that five out of the six patients with the	
5	me to what extent surgeons well, rephrase.	5	persistent dyspareunia had pre-existing chronic pain	
6	Do you have any opinion as to whether or to	6	of one sort or another because you saw an association	
7	what extent surgeons in general who would consider	7	between the two; otherwise, you wouldn't have	
8	using the Prolift® have been aware of potential the	8	commented on it, correct?	
9	potential risks to younger, sexually active women from	9	MR. SNELL: Objection, form.	
10	Prolift® complications?	10	THE WITNESS: Correct.	
11	A. Let me answer this way: We don't live in a	11	BY MR. SLATER:	
12	bubble. There's a chance for discomfort with	12	Q. When was it that you first started to become	
13	intercourse after any pelvic surgery that you do,	13	aware of a potential association between chronic pain	
14	okay. Over the past few years, specifically since	14	and Prolift® complications?	
15	2008, when the first FDA notification came out, there	15	A. I would never say that I've had that	
16	is certainly a growing amount of concern regarding	16	particular whatever term you used, feeling. That's	
17	liability when you're using a permanent material in	17	generally something that I've felt any surgery is	
18	someone, okay, a mesh placed transvaginally, because	18	going to be a risk for having that outcome.	
19	that's what the FDA came out within 2008.	19	Q. When the Prolift® mesh is placed in the body	
20	Because of that, who are more likely to have	20	and creates irritation rephrase.	
	pain with intercourse? People that are younger,	21	When the Prolift® mesh is placed in the body	
21			•	
22	generally. I have some older patients that have sex	22	and creates inflammation and if a person is up	
23	every day, but, you know, generally, younger patients	23	regulated due to a pain condition that they previously	
24	are more likely to be more frequently sexually active	24	had so that they're more susceptible, that	
25	and, therefore, that complication of dyspareunia,	25	inflammation can interact with the nerves and create	
	Page 203			Page 205
1	Page 203 which, again, can occur with any procedure is going to	1	more pain than if the patient didn't have that	Page 205
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	Page	e 206	Ι	Page 208
		200		age 200
	performed on her; isn't that true?		1 MR. SNELL: Objection, form.	
2	A. Yes, and that involves incisions.		2 BY MR. SLATER:	
3	Q. Right. The incisions that are done in		3 Q. By definition.	
4	accordance with the Prolift® procedure, correct?		4 A. I think by the definition of your	
5	A. Correct.		5 hypothetical situation, correct.	
6	Q. And the incisions are not identical between		6 Q. Okay. And for that woman in this	
7	the Prolift® procedure and, for example, colporrhaphy		7 hypothetical, you can't say, well, if she had had	
8	or ligament fixation, correct?		8 colporrhaphy or she had suture fixation, she would	
9	A. Depends on who is doing the surgery.		9 have ended up with the same complications, you can't	
10	Q. Okay. And the dissections are not the same	-	10 say that. That would be speculative, right?	
11	as between the Prolift® procedure and native tissue	-	11 MR. SNELL: Objection, form.	
12	repair; the dissections are different, correct?	:	12 THE WITNESS: Right.	
13	A. They are.	:	13 BY MR. SLATER:	
14	Q. And the introduction of the large mesh	:	Q. You can say there are risks with these other	
15	implant when it's placed in the woman's body is	:	15 procedures, which may have some of the same symptoms,	
16	different than traditional suture repair because in	:	16 but you can't it would be pure speculation to say	
17	those procedures you're not putting the mesh implant	:	17 those things would have actually occurred if a	
18	in the body, correct?	-	18 different operation was performed, correct?	
19	MR. SNELL: Objection, form.	:	19 A. Of course.	
20	THE WITNESS: Yes.	2	20 MR. SLATER: Why don't we take a break.	
21	BY MR. SLATER:		21 THE VIDEOGRAPHER: We're going off the	
22	Q. So there are significant differences in		22 record. The time is 1:51 p.m.	
23	terms of the actual procedure and what is actually		23 (Luncheon recess.)	
24	done inside the woman's body as between the Prolift®		24 THE VIDEOGRAPHER: We're back on the	
25	procedure and traditional suture repair, correct?	1	25 record. Here marks the beginning of Volume 1 in Tape	
	Page	e 207	F	Page 209
1	A. Yes, but you keep saying we're not talking	e 207	1 Number 4 in the deposition of Dr. Miles Murphy. The	Page 209
1 2		e 207		Page 209
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	Confidencial - Subject to Scipula		
	Page 210		Page 212
1	A. My involvement was it involved outcomes of a	1	to take a break.
2	number of my patients. I helped with the statistics.	2	THE VIDEOGRAPHER: Going off the
3	I may have helped with the data collection, edited the	3	record, the time is 2:43 p.m.
4	manuscript.	4	(Brief recess.)
5	Q. Now, if you turn to the second page, there's	5	THE VIDEOGRAPHER: We're back on the
6	a bit of information provided. The materials and	6	record. Here marks the beginning of Volume 1 and Tape
7	methods says that this only included patients who had	7	Number 4 in the deposition of Dr. Miles Murphy. The
8	a minimum of one-year follow-up, correct?	8	time is 2:55 p.m.
9	A. Yes.	9	BY MR. SLATER:
10	Q. And then if you go to the results section,	10	Q. Doctor, I had shown you earlier in the
11	it says 151 patients met the inclusion criteria and	11	deposition Exhibit 899, the e-mail that Piet Hinoul
12	their surgeries were performed between February 2005	12	wrote where he stated, who believes Mr. Lucente's
13	and August 2006, correct?	13	group when Van Raalte publishes that they have no
14	A. Correct.	14	erosions? Nobody.
15	Q. And then you go through the results and talk	15	In this article you and your group, which is
16	about different results throughout that section, and I	16	Van Raalte and the group, as he states, correct?
17	want to draw your attention to the last column, the	17	A. Correct.
18	end of the first long paragraph right in the middle of	18	Q. Reported that 97 women with at least one
19	the page.	19	year of follow-up had zero erosions or exposures,
20	Do you see that?	20	correct?
21	A. Mm-hmm.	21	A. Correct.
22	Q. There's a sentence that says, "no mesh	22	Q. Do you stand by the report in this article
23	exposures or erosions were detected."	23	that there were no mesh exposures or erosions for any
24	Do you see that?	24	of those 97 patients over the course of a year?
25	A. I do.	25	A. I would just say, to the best of our
		1	
	Page 211		Page 213
1	Page 211 O Is that a statement that of the 151 patients	1	Page 213
1 2	Q. Is that a statement that of the 151 patients	1 2	knowledge, there were none.
2	Q. Is that a statement that of the 151 patients who were included in the study, not one of them had a	2	knowledge, there were none. Q. Well, what does that mean to the best of
2 3	Q. Is that a statement that of the 151 patients who were included in the study, not one of them had a mesh exposure or an erosion at any point during that	2 3	knowledge, there were none. Q. Well, what does that mean to the best of your knowledge?
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	Page 214			Page 216
	exists if it can actually be seen with the eye on an	1		
	exam?	2	patients, had at least one year follow-up with no	
3	A. For the purposes of reporting erosion and	3	erosions and no exposures?	
4	exposure rates, I would say that is correct.	4	A. For Prolift®?	
5	Q. If there's a development of granuloma	5	Q. Start with Prolift®.	
6	tissue, is that reported separately as a different	6	A. No, I can't think of any.	
7	finding than an exposure in your group?	7	Q. How about with regard to any transvaginally	
8	A. It would be, yes.	8	placed synthetic mesh for the treatment of prolapse?	
9	Q. Granuloma tissue is what in this context?	9	A. I know that in some of the I was involved	
10	A. Red beefy tissue that looks different than	10	in a systematic review group as part of the Society	
11	the average vaginal lining.	11	for Gynecologic Surgeons, and one of the offshoots of	
12	Q. And what is the association between	12	one of our projects was looking at adverse outcomes	
13	granuloma tissue and exposure?	13	with transvaginal mesh for Prolift®, so I believe Sam	
14	A. You can have granulation tissue overlying an	14	Abed was the lead author on that. I know that we list	
15	exposure that you can't see.	15	zero to, you know, something like 25, 30% erosion	
16	Q. Was any granulation tissue reported in this	16	rates across the studies. I'm not sure what that	
17	study?	17	zero, if that was specifically referring to this one	
18	A. I don't recall. I'd have to read through	18	or not.	
19	the results.	19	I do know of studies like Withagen study	
20	Q. If you can take a quick look, I'm curious if	20	where they looked at different as a multi-center	
21	you can point to anything like that.	21	study and they looked at certain centers, and certain	
22	A. I don't see any tables that list that. Let	22	centers had zero percent erosion rates in a year. I	
23	me look in the results. (Witness reviews document.)	23	don't know if there's any published study where the	
24	I just scanned through the results section,	24	total population was zero, though, other than what I	
25	and I don't see anything regarding granulation tissue.	25	just referred to in that review.	
	Page 215			Page 217
1	Q. Do you have any recollection of whether or	1	Q. On Page e4, actually e5 of this article in	
2	not, as part of this study, you and your partners	2	the left column, you refer to bunching of mesh.	
3	looked for granulation tissue?	3	What does that mean?	
4	A. As part of the study, I don't recall	4	A. It means that rather than lying flat, the	
5	specifically. I know that in the in some research	5	mesh is bunched.	
6	that we've done, we've reported on granulation tissue,	6	Q. Why does that happen with the Prolift®?	
7	but I don't recall if we would have specifically	7	A. It could happen most likely I would think	
8	looked at that as an outcome in this procedure in	8	that too large of an area of mesh was placed in too	
9	this study, excuse me.	9	small of an area of the patient's spaces, anatomic	
10		1		
	Q. Are you aware of any other published study	10	spaces. That would be the main reason that I can	
11	Q. Are you aware of any other published study in existence in the peer-reviewed medical literature	10 11	spaces. That would be the main reason that I can think of.	
11 12			•	
	in existence in the peer-reviewed medical literature	11	think of.	
12	in existence in the peer-reviewed medical literature where 97 or close to that number of patients had at	11 12	think of. Q. One of the areas of medical judgement that	
12 13	in existence in the peer-reviewed medical literature where 97 or close to that number of patients had at least one-year follow-up and not one patient had an	11 12 13	think of. Q. One of the areas of medical judgement that is brought to bear on a Prolift® procedure is the	
12 13 14	in existence in the peer-reviewed medical literature where 97 or close to that number of patients had at least one-year follow-up and not one patient had an exposure? Is there any other article that you can	11 12 13 14	think of. Q. One of the areas of medical judgement that is brought to bear on a Prolift® procedure is the surgeon's decision as to whether or to what extent to	
12 13 14 15	in existence in the peer-reviewed medical literature where 97 or close to that number of patients had at least one-year follow-up and not one patient had an exposure? Is there any other article that you can point to anywhere in the published literature ever?	11 12 13 14 15	think of. Q. One of the areas of medical judgement that is brought to bear on a Prolift® procedure is the surgeon's decision as to whether or to what extent to cut the mesh down and trim the mesh down, correct?	
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	Page 2			Page 220
1	Q. And what is it you are seeking to accomplish		probably wouldn't work as well as if you didn't have	1 agc 220
1	with trimming the mesh?			
2	A. To have there not be excess mesh where there	2	Q. If there's excess mesh, can that contribute	
3	isn't room for it.	3		
4		4		
5	Q. When you refer to "excess mesh," it may seem	5	A. How do you define "failure"?	
6	very obvious to you and seem basic, but I want to make	6	Q. Recurrence of the prolapse.	
7	sure we're on the same page. What does that mean?	7	A. I wouldn't think so. I can't really think	
8	A. Well, for instance, the Prolift® it's easy	8	of a situation where that would be the case.	
9	to cut away from it. You can't really add to it. So	9	Q. If there's excess mesh, could that	
10	they're going to make it long, so if someone has a	10	contribute to erosion?	
11	particularly long vagina, that Prolift® mesh will fit.	11	A. I think potentially it could, yeah.	
12	But if someone has a shorter vaginal length, you can	12	Q. If there's excess mesh and it leads to	
13	trim it to fit the patient, and so, in general, it	13	•	
14	just makes sense to have more mesh on the initial	14	have bunched mesh inside the woman's pelvis, what can	
15	potential implant and cut away from that.	15	that cause?	
16	Q. When you refer to not wanting to leave any	16	A. Well, again, like I said	
17	excess mesh, what does that mean in terms of to you as	17	MR. SNELL: Objection, form. Go ahead.	
18	a surgeon, if there's excess mesh, what is it that's	18	THE WITNESS: Again, it just wouldn't	
19	going on and what's the problem with that?	19	let the vaginal wall lay as flat as it normally would.	
20	A. Just like noses or, you know, ears, some	20	BY MR. SLATER:	
21	people have big ones, some people have small ones,	21	Q. The intent of the Prolift® is for the mesh	
22	they're shaped different ways. It's the same with	22	•	
23	vaginas. Vaginal lengths, widths, calibers are all	23	A. As in terms of where it is in the relation	
24	different. So it just wouldn't make sense to put a	24		
25	10-centimeter strip of mesh in someone with a	25	Q. And if the mesh does not lay flat, it's not	
	Page 2	9		Page 221
1	Page 2. 9-centimeter vagina.	9 1	functioning as intended because it's not in the	Page 221
1 2				Page 221
	9-centimeter vagina.	1		Page 221
2	9-centimeter vagina. Q. What is the risk to the patient if excess	1 2	position that was intended, correct?	Page 221
2 3	9-centimeter vagina. Q. What is the risk to the patient if excess mesh is there, if the mesh implant is too big for the	1 2 3	position that was intended, correct? MR. SNELL: Objection, form. THE WITNESS: I think that's pretty	Page 221
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			- Contraction	
	Page 222			Page 224
1	Q. The evaluation of how much to trim the mesh	1	Q. Are you aware of anybody within Ethicon	
2	will depend on the surgeon's judgement in evaluating	2	that's ever held that viewpoint that that is a risk?	
3	the patient at the time of the surgery and deciding	3	A. I'm not aware of that.	
4	how to trim the mesh right there in the operating	4	Q. Are you aware of any literature that	
5	room, correct?	5	discusses that issue?	
6	A. Yes.	6	A. Of trimming too much mesh, I am not.	
7	Q. There are no objective standards one could	7	Q. Other than a surgeon's subjective judgement	
8	look to to say, well, you know, I need to trim this	8	at the time of the surgery, would the surgeon have	
9	Prolift® this much in order for it to work best with	9	anything else to go on in determining how much and	
10	this woman's anatomy, that's not something that's	10	what parts of the Prolift® to trim?	
11	taught; that's not something that is out there to be	11	A. Usually when most people first start using	
12	objectively learned, right?	12	Prolift®, they go to when people did start using	
13	A. It's certainly taught that you want to trim	13	Prolift®, they went to professional education, cadaver	
14	it so it lays in a flat manner, but it's not like you	14	labs, lectures, things of that nature, precepting,	
15	can have a POP-Q of something and say when these POP-Q	15	proctorship, and, generally, the leader, the teacher	
16	numbers are this way, you can plug it into a computer	16	in that situation would give their own sort of	
17	and it tells you how to cut the mesh.	17	opinions as to what might be a good amount to trim	
18	Q. Would you agree with me an important part of	18	here or there.	
19	the Prolift® procedure is in the vast majority of	19	Q. So those would be essentially general	
20	surgeries, unless the Prolift® that came out of the	20	recommendations on what to do if you're going to trim	
21	box happens to be the perfect size for that woman, is	21	the mesh?	
22	to appropriately trim the mesh so that you get the	22	A. Yeah.	
23	right fit?	23	Q. And those recommendations would vary most	
24	A. Yes. I think it's one of the important	24	likely from preceptor to preceptor or proctor to	
25	steps in making it work properly.	25	proctor, right?	
	Page 223			Page 225
1	Page 223 O. Are there risks if one were to trim the mesh	1	A. To a certain degree, yes, it would probably	Page 225
1 2	Q. Are there risks if one were to trim the mesh	1 2	A. To a certain degree, yes, it would probably vary.	Page 225
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	Confidential - Subject to				
		Page 226			Page 228
1	what they should be looking for in order to be able to		1	Q. As an expert in this case, do you agree with	
2	confirm yes, this is a tension free placement of the		2	the proposition that surgeons utilizing the Prolift®	
3	Prolift®?		3	had varying skill levels?	
4	A. What do you mean by "copy reviewed"?		4	A. Yes.	
5	Q. Something that's an official Ethicon		5	Q. Do you agree that the surgeons have varying	
6	document, something that Ethicon promulgates saying		6	levels of training?	
7	this is what Ethicon is saying to doctors.		7	A. Yes.	
8	MR. SNELL: Objection to form.		8	Q. Do you agree that the quality of the	
9	THE WITNESS: Yeah, I can't		9	training that surgeons using the Prolift® rephrase.	
10	definitively recall. I mean, I think in some of the		10	Would you agree that for surgeons using the	
11	professional education slides, there may be talk		11	Prolift®, the quality of their training, however you	
12	about, you know, making sure that you don't over		12	would define high quality training and maybe not as	
13	tension the mesh, but I couldn't refer you to a		13	good quality, varies from surgeon to surgeon in many	
14	specific file.		14	cases?	
15	BY MR. SLATER:		15	MR. SNELL: Objection, form.	
16	Q. Is there any objective standard you can		16	BY MR. SLATER:	
17	point to whereby Ethicon ever explained what a doctor		17	Q. And I'm talking about their training to	
18	should be rephrase.		18	become a surgeon and then the training they get after	
19	To your knowledge, is there any Ethicon		19	that.	
20	document or source of information where Ethicon		20	MR. SNELL: I'm going to object to	
21	explained, this is how you can objectively verify that		21	form. You're not talking about training on Prolift®,	
22	you have a tension free placement that's proper for		22	you're just talking their general training?	
23	this Prolift®? Is there any way to objectively verify		23	BY MR. SLATER:	
24	it that Ethicon has told surgeons?		24	Q. I'm not talking about Ethicon's professional	
25	MR. SNELL: Objection, form. Go ahead.		25	education right now. I'm talking about general	
23	With STALLE. Cojection, form. Go ancad.		23	eddeation right now. The tanking about general	
		Page 227			Page 229
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1 2	THE WITNESS: I don't know that there is a known perfect way to place it.	Page 227	1 2		Page 229
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,	lavel of skill is needed in order to perform Prolift®	1 age 230	,	my vision ion't as good, and avantually my avnationes	1 age 232
	level of skill is needed in order to perform Prolift®		1	my vision isn't as good, and eventually my experience	
2	surgery?		2	will have me have worse outcomes, but, yes, the more	
3	MR. SNELL: Objection, form.		3	of any procedure, including Prolift®, that you do,	
4	THE WITNESS: I don't know what you		4	probably the better you're going to be at it.	
5	mean by high. No, I think that there's probably		5	MR. SLATER: Move to strike.	
6	people that I would consider maybe not quite as good a		6	BY MR. SLATER:	
7	surgeon as someone else, and they would get good		7	Q. Is the answer to my question yes?	
8	results with Prolift® too.		8	A. You'd have to repeat the question.	
9	BY MR. SLATER:		9	MR. SNELL: Object to form.	
10	Q. Do you think that there is a correlation		10	BY MR. SLATER:	
11	between a surgeon's skill level and the outcomes they		11	Q. In your opinion, is there a correlation	
12	will get with the Prolift®? Do you have an opinion to		12	between the number of Prolift® procedures a surgeon	
13	a reasonable degree of medical probability one way or		13	has performed and the outcomes that that surgeon will	
14	the other on that question?		14	obtain?	
15	A. I have never seen a study that looked		15	MR. SNELL: Objection, form, asked and	
16	specifically at Prolift®. I think there are studies		16	answered.	
17	out there that show that, for instance, if you do a		17	THE WITNESS: Yes.	
18	lot of vaginal hysterectomies in a year, you're going		18	BY MR. SLATER:	
19	to have less complications than someone who does only		19	Q. Do you have an opinion as to how many	
20	a handful. So, yes, that would probably apply to		20	procedures it takes for a surgeon to get through	
21	Prolift® as well.		21	well, rephrase.	
22	Q. So, in your opinion, a surgeon's skill level		22	Are there different stages of the learning	
23	will have a correlation to the surgeon's outcomes with		23	curve with the Prolift®, in your opinion?	
24	the Prolift®, correct?		24	A. As with all surgeries, yes.	
25	MR. SNELL: Objection, form.		25	Q. I'm not asking about any other surgeries,	
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		Page 231			Page 233
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1 2	THE WITNESS: I don't know. I mean, that's not a crazy supposition, but I don't know that	Page 231	1 2	with all due respect, so let's just stick to the Prolift® now, okay?	Page 233
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	Page 234			Page 236
1	record as requested.)	1		
2	BY MR. SLATER:	2	experience and skill level of the surgeon coming into	
3	Q. In your opinion, are there different stages	3	the first time they try to do a Prolift, correct?	
4	of the learning curve with the Prolift® procedure?	4	A. Correct.	
5	MR. SNELL: Objection, form.	5	Q. Let's look at the article that you have in	
6	THE WITNESS: Yes.	6	front of you, Exhibit 1216. Again, we're on page e5.	
7	BY MR. SLATER:	7	Look at the third column, right-hand side down the	
8	Q. How would you break that down?	8	very bottom. One of the things that you and your	
9	A. I would say that the very first time someone	9	co-authors state is "there is also a need for	
10	does a Prolift® procedure, they are probably more	10	long-term follow-up to evaluate the potential for	
11	likely to encounter difficulties than the	11	delayed complications, such as late-onset graft	
12	one-hundredth one that they've done.	12	infection, exposure or visceral erosion."	
13	In terms of actual stages, I know that	13	Do you see that?	
14	somewhere I've been an author on a paper where it said	14	A. Yes.	
15	somewhere along the lines of 20 I don't know if it	15	Q. And that was an opinion that you held at the	
16	was a paper or not, but it was something I reviewed in	16	time that you co-authored this article, correct?	
17	this process, where I said 20 to 30 is probably when	17	A. Yes.	
18	you're getting a high level of familiarity and comfort	18	Q. And that was in December 2008 when this was	
19	with it, something along those lines. I don't recall	19	published?	
20	exactly what I said.	20	A. Yes.	
21	Q. The learning curve will vary beyond those	21	Q. What is late-onset graft infection?	
22	general numbers on a surgeon by surgeon basis,	22	A. Well, it's something I've never seen, but it	
23	correct?	23	would imply that the mesh becomes infected sometime	
24	A. I think that's fair to say.	24	after the early postoperative period.	
25	Q. Was it important well, rephrase.	25	Q. You've indicated during the deposition	
	Q. Was a important went, replicated		Q. Tour to material during the deposition	
	Page 235			Page 237
1	Page 235 Is the Prolift® complex pelvic	1	several times that there were risks or complications	Page 237
		1 2	several times that there were risks or complications that I've raised with you that you hadn't seen in your	Page 237
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2	Is the Prolift® complex pelvic reconstructive surgery?	2	that I've raised with you that you hadn't seen in your	Page 237
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1	life some type of organism that would be adhered or	1	Q. One way or the other, you don't know one way	
2	near the mesh.	2	or the other?	
3	Q. Did you see the term biofilm in any of the	3	MR. SNELL: Object to form.	
4	deposition testimony? Did you see that described by	4	THE WITNESS: Again, all I know is that	
5	any of the Ethicon witnesses in any of the	5	I've put in hundreds of Prolifts®, and I would think	
6	depositions?	6	if there was a low grade infection, we'd see sequelae	
7	A. I don't recall seeing that.	7	of that.	
8	Q. Did you see the term biofilm discussed in	8	BY MR. SLATER:	
9	any of Ethicon's internal documents?	9	Q. It could be that your technique is better	
10	A. I don't recall seeing that.	10	than other surgeons and you have less complications;	
11	Q. Do you know whether or not the medical	11	that's possible, right?	
12	affairs people in Ethicon believe that a biofilm can	12	A. Well, what I would say is, you know,	
13	form on a Prolift® and lead potentially to	13	theoretically, the people that believe that type of	
14	complications for a patient?	14	thing think that that's what leads to erosions and	
15	A. I don't recall seeing that.	15	that it would lead to late erosions. So, again, what	
16	Q. Is that a subject about which you have very	16	I would care about is what the rate of late erosion	
17	little familiarity, the concept of biofilm and what		was.	
18	that can lead to?	18	Q. You're not familiar rephrase, withdrawn.	
19	MR. SNELL: Objection to form.	19	At the time that the Prolift® was first	
	THE WITNESS: I have familiarity with		launched, you would agree with me that there was no	
20	·	20		
21	the theory put forth by a number of the plaintiffs'	21	long-term data with regard to the Prolift®, correct?	
22	experts that once you put a mesh in through the	22	MR. SNELL: Objection, form.	
23	vagina, it's going to be contaminated, there's going	23	THE WITNESS: It would depend what you	
24	to be potential of having bacteria there and that you	24	mean by Prolift®, and it would depend what you mean by	
25	could have a low grade infection or, you know,	25	long-term.	
	Page 239		Page 24	41
1	Page 239 bacteria there that wouldn't have been there otherwise	1	Page 24 BY MR. SLATER:	41
		1 2		41
	bacteria there that wouldn't have been there otherwise		BY MR. SLATER: Q. Well, how would you define long-term data	41
2	bacteria there that wouldn't have been there otherwise indefinitely. BY MR. SLATER:	2	BY MR. SLATER: Q. Well, how would you define long-term data with regard to studies of the Prolift®?	41
2 3 4	bacteria there that wouldn't have been there otherwise indefinitely. BY MR. SLATER: Q. With regard to what you just stated, do you	2 3 4	BY MR. SLATER: Q. Well, how would you define long-term data with regard to studies of the Prolift®? A. I would tend to say that some people,	41
2 3 4 5	bacteria there that wouldn't have been there otherwise indefinitely. BY MR. SLATER: Q. With regard to what you just stated, do you agree that can happen?	2 3 4 5	BY MR. SLATER: Q. Well, how would you define long-term data with regard to studies of the Prolift®? A. I would tend to say that some people, including myself, at times would consider one year	41
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	Page 242			Page 244
	1 permanent implant	1	Q. That's the person we talked about earlier,	
	2 A. Yes.	2	Graeme Scott that you couldn't remember his name from	
	Q and that presents risks of complications	3	Scotland, or you don't know?	
	4 years in the future, one year is not long term,	4	A. I don't know. Very possible, I guess.	
	5 correct?	5	Q. These are the minutes of a meeting that you	
	MR. SNELL: Objection, form.	6	attended on February 2, 2006, correct? That's what it	
	7 THE WITNESS: I think that that's	7	says.	
	somewhat reasonable, yes.	8	A. Yes. I mean, that's what it says right	
	BY MR. SLATER:	9	here. I'm not sure that's when this was drafted or	
1	Q. When the Prolift® was launched, there was no	10	that's when the meeting was, probably pretty close.	
1	long-term data with regard to the Prolift® system as	11	Q. You were discussing the possibility of a	
1	2 it was marketed in the box with the Prolift® procedure	12	Prolift® RCT being structured and performed, correct?	
1	3 and instruments, correct?	13	A. Correct.	
1	4 MR. SNELL: Objection to form. Go	14	Q. Was that ever done?	
1	5 ahead.	15	A. No, not by Ethicon.	
1	THE WITNESS: In the sake of time,	16	Q. Was there ever a registry developed with	
1	7 again, I will give to you that at the time the	17	regard to the Prolift®?	
1		18	A. Sponsored by Ethicon?	
1		19	Q. Let's start with sponsored by Ethicon.	
2		20	A. Not that I'm aware of.	
2	. t	21	Q. Was there a Prolift® registry in existence	
2		22	anywhere?	
2		23	A. I guess depends by how you define	
2		24	"registry."	
2		25	Q. Did your group have a registry?	
1-	<u>.</u>			
	Page 243			Page 245
	Page 243 were eventually marketed as part of the kit, correct?	1	A. We did not have a registry. We made an	Page 245
		1 2	A. We did not have a registry. We made an early on decision that we would like to look to	Page 245
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		D 246			D 240
		Page 246			Page 248
1	A. Yeah, I I mean, vaguely, I may have		1	decision, would you?	
2	you know, this was six years ago, seven years ago. I		2	MR. SNELL: Objection, form.	
3	may have heard some discussion about potentially		3	THE WITNESS: I'm a doctor, I like to	
4	having a registry, but I certainly don't know why they		4	have my decisions being made on medicine as much as I	
5	decided not to, if they had been thinking about doing		5	can.	
6	it.		6	BY MR. SLATER:	
7	Q. In some ways a registry gives very useful		7	Q. As an expert who has put himself out to give	
8	data because you're getting results from surgeons of		8	opinions about the propriety of what a medical device	
9	varying backgrounds and skill levels as opposed to		9	manufacturer did, would you agree with me that that	
10	just those surgeons who actually will routinely		10	would be improper if that was the decision why Ethicon	
11	conduct clinical trials and maybe the higher skilled		11	chose not to conduct a registry?	
12	surgeons, correct?		12	MR. SNELL: Objection, form.	
	·			·	
13	MR. SNELL: Objection, form.		13	THE WITNESS: Because they didn't want	
14	BY MR. SLATER:		14	it known that there were more complications than with	
15	Q. You understand what I'm getting at?		15	a different device?	
16	A. Because we've made this distinction between		16	BY MR. SLATER:	
17	TVM and Prolift®, I want to be answering your		17	Q. Because they didn't want it to be perceived	
18	questions about Prolift® as the actual kit Prolift®.		18	that because they were collecting more information	
19	Q. That's what I'm asking about.		19	about the Prolift® than their competitors were about	
20	A. Okay. But I want to put on the record as my		20	the competitive products that it might be perceived	
21	opinion that what is being left in that patient		21	that there was a higher level of complications; that	
22	polypropylene mesh that's of large porosity and		22	would be wrong?	
23	monofilament in the shape that Prolift® is was done in		23	MR. SNELL: Same objection.	
24	the TVM study in that over 700 patients that they		24	THE WITNESS: That would disappoint me.	
25	followed or over 600 patients that they followed in		25	I don't know that it's wrong.	
		D 047			D 240
		Page 247			Page 249
1	TVM.	Page 247	1		Page 249
1 2	TVM. MR. SLATER: Move to strike.	Page 247	1 2	Q. It would disappoint you, though?	Page 249
		Page 247			Page 249
2	MR. SLATER: Move to strike.	Page 247	2	Q. It would disappoint you, though?	Page 249
2 3 4	MR. SLATER: Move to strike. BY MR. SLATER:	Page 247	2	Q. It would disappoint you, though?A. Yeah, it would disappoint me.	Page 249
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	Confidencial - Subject to Scipula		
	Page 250		Page 25
	I'm a doctor. I want as much data as I can, but		back on and say we have a good idea of what's been
2	studies cost money, and if you're going to do a study	2	going on, correct?
3	that you think because it isn't necessarily going to	3	MR. SNELL: Objection, form.
4	demonstrate to the public eye something poor, then you	4	THE WITNESS: I think they were doing
5	might not want to do it. That doesn't mean that I	5	that in following TVM patients. Even though you seem
6	think that that would be an irresponsible thing an	6	to think there's a huge difference between the
7	irresponsible decision for the company.	7	Prolift® kit and TVM, as a doctor, as an expert, I
8	MR. SLATER: Move to strike.	8	don't see a big difference there.
9	BY MR. SLATER:	9	BY MR. SLATER:
10	Q. As an expert forming an opinion as to	10	Q. Was there a difference in the instruments
11	whether or not Ethicon acted appropriately in studying	11	between TVM and Prolift®?
12	the potential risks and complications with the	12	A. A small difference, yes.
13	Prolift®, if they decided not to have a registry	13	Q. That's your understanding, it was a small
14	because someone in medical affairs said, well, that's	14	difference?
15	going to make our complication rates look higher and	15	A. It's not my understanding. It's what I
L6	worse than competitors, so let's not do it because		know.
L 7	that will hurt us from a marketing standpoint, what	17	Q. Do you think the tools, the instruments used
18	would you have to say about that?	18	in the TVM study were good instruments, good tools?
19	MR. SNELL: Objection, form.	19	A. I think they were good. I think the
20	THE WITNESS: I would say that I want	20	Prolift® instruments were better for the procedure.
21	the most data I can get.	21	Q. Let's look at Exhibit 2002, the notes from
	BY MR. SLATER:	22	the February 2, 2006 meeting. If you could turn to
23	Q. And you would say to Ethicon, you should		the second page, there's a statement attributed to
	have done the registry, so what if the other people	23	Vincent Lucente that says "dyspareunia is more likely
		24	• • • •
25	aren't doing the registry, give the information to the	25	from posterior incisions."
	Page 251		Page 25
1	other doctors and stand behind your product, right?	1	Is that something you agree with with the
1 2	other doctors and stand behind your product, right? Isn't that what you would say?	1 2	Is that something you agree with with the Prolift®?
	• •		<i>。</i>
2	Isn't that what you would say?	2	Prolift®?
2 3 4	Isn't that what you would say? MR. SNELL: Object to form. Go ahead.	3	Prolift®? MR. SNELL: What page are you on? I'm
2 3 4 5	Isn't that what you would say? MR. SNELL: Object to form. Go ahead. THE WITNESS: Not necessarily. I mean,	2 3 4	Prolift®? MR. SNELL: What page are you on? I'm sorry.
2 3 4 5 6	Isn't that what you would say? MR. SNELL: Object to form. Go ahead. THE WITNESS: Not necessarily. I mean, I'm a doctor. I don't rely on Ethicon to do	2 3 4 5	Prolift®? MR. SNELL: What page are you on? I'm sorry. BY MR. SLATER:
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	Page 254			Page 256
1	A. With Prolift® or just	1	know if I would say constant pain for two weeks since	
2	Q. With Prolift®.	2	the surgery, no. Can I I'll answer that question	
3	A. Not that I'm aware of.	3	more specifically. I have never operated on someone	
4	Q. Down further there's a heading, "Recent	4	who has been in constant pain two weeks after a	
5	Problem with Prolift®" and it says according to	5	surgery for a Prolift®.	
6	Dr. Lucente "recently removed the center of an	6	Q. Let me ask the question clean, just because	
7	anterior Prolift® from a Tennessee woman. The device	7	we kind of went around a little bit.	
8	appeared to have been placed too tightly. Patient was	8	A. Okay.	
9	in constant pain and had been since two weeks	9	Q. This document refers to a patient being in	
10	post-surgery," and then Dr. Lucente apparently said,	10	constant pain beginning two weeks after the Prolift®	
11	"returning for surgery to deal with a bad Prolift®	11	surgery.	
12	will be a disaster. It must be fitted with slack."	12	Have you ever had to operate on a patient to	
13	Do you see that?	13	remove part of a Prolift® implant where a patient had	
14	A. I do.	14	constant pain following the procedure up till the	
15	Q. And do you agree where you have to return	15	surgery?	
16	for surgery to deal with what he terms a bad Prolift®	16	A. Up until my revision surgery, no, I do not	
17	which is here described as one that was placed too	17	recall ever having to do that.	
18	tightly, that that is a disaster?	18	Q. The one patient where you had to release the	
19	A. I don't know in what context he's talking	19	deep arm, was that a patient that was in constant	
20	about it will be a disaster. I don't know if it's in	20	pain?	
21	regard to if there's a study or just in general it's a	21	A. I wouldn't say constant, no.	
22	disaster, without having read the whole document, but	22	Q. So you have no experience personally with	
23	I agree that's what he said. There's no question	23	the removal of mesh from a patient suffering from	
24	that's what he said.	24	constant pain from a point after the Prolift®	
25	Q. When a patient has to be re-operated on for	25	procedure forward to the time of the surgery; that's	
	D 055			D 257
	Page 255			Page 257
	a Prolift® that's causing constant pain in a patient,		not something you've done, correct?	Page 257
2	a Prolift® that's causing constant pain in a patient, the surgery to try to remove parts of the Prolift® can	2	MR. SNELL: Objection, form.	Page 257
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	Page 258			Page 260
1	THE WITNESS: So in this case I have	1	THE WITNESS: You said a lot of things	
2	reviewed the testimony of some of the experts about	2	there. I generally agree with the general sentiment	
3	one of the patients who had multiple surgeries, so I	3	that you're saying.	
4	know that they exist. I know that there are patients	4	BY MR. SLATER:	
5	like that.	5	Q. And you would agree with me that as a	
6	BY MR. SLATER:	6	patient faces that type of a situation, it's	
7	Q. When that happens to patients like that,	7	essentially a catch 22 because you're kind of damned	
8	that is	8	if you do and damned if you don't. If you don't do	
9	A. That's a horrible outcome.	9	the surgery, you may just live with this pain forever,	
10	Q. The patient you're talking about, is that	10	and if you do do the surgery and try to treat further,	
11	Linda Gross?	11	it might help you, but it also might make you worse?	
12	A. Yes.	12	Would you agree with that, that that's a catch 22 the	
13	Q. You would agree Linda Gross has had a	13	patient is faced with?	
14	horrible outcome, correct?	14	MR. SNELL: Object to form. Go ahead.	
15	A. I would agree that	15	THE WITNESS: It's a difficult	
16	MR. SNELL: I'm going to object to	16	situation for a patient.	
17	go ahead.	17	BY MR. SLATER:	
18	THE WITNESS: I would say that what she	18	Q. Are you aware of whether Ethicon was aware	
19	has gone through, best as I can tell from reading	19	at the time that the Prolift® was first launched that	
20	these reports, is something that no patient would want	20	there were patients who were going to end up in that	
21	to have to go through.	21	type of a situation?	
22	MR. SLATER: Okay. And just I only	22	A. I don't know what Ethicon knew.	
23	followed up on it because he mentioned it. I'm not	23	Q. Certainly, if Ethicon was aware that that	
24	going any further into it.	24	would be happening to some number of patients, you	
25	MR. SNELL: He hasn't served a report	25	would want Ethicon to make sure they clearly	
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	Page 259			Page 261
1	Page 259 in the Gross case.	1		Page 261
1 2		1 2		Page 261
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				.04
	individual judgement in a situation like that,	1	THE WITNESS: I'm sorry. Repeat that.	
2	correct?	2	I drifted there for a second.	
3	A. Correct.	3	BY MR. SLATER:	
4	Q. Some surgeons would be more willing than	4	Q. When Ethicon markets that Prolift® to	
5	others to do more radical or more invasive surgery	5	physicians, Ethicon is saying to physicians, here,	
6	based on whatever is entering into their own	6	this is a system that we're telling you is safe and	
7	judgement, correct?	7	effective to use with your patients, correct?	
8	A. I would guess so. I can't speak for other	8	A. I assume that's what I mean, they don't	
9	surgeons, but I would think that would be reasonable.	9	say that when they but, yes, it's implied.	
10	Q. Did Ethicon ever promulgate any instructions	10	Q. It's implied?	
11	or warnings to surgeons on how to safely or most	11	A. Yes.	
12	safely remove Prolift® mesh or parts of the mesh, if	12	Q. And Ethicon sends the IFU along with the	
13	necessary, to treat complications?	13	Prolift® to tell doctors here are the	
14	A. The first part was did they ever communicate	14	contraindications, the warnings, the adverse events,	
15	it to	15	the risks that we know of with regard to the Prolift®,	
16	Q. Promulgate, put out, communicate to doctors.	16	and here is the list so that you can take this into	
17	A. Outside of well, I think part of the	17	account, correct?	
18	professional education in terms of people coming to	18	A. They do provide an IFU, and in that is	
19	lectures and doing cadaver labs, part of that would	19	potential complications with the procedure.	
20	have been talking about correcting mesh erosions,	20	Q. And one of the things that Ethicon knew from	
21	taking out mesh.	21	the day that it marketed the Prolift® was that some	
22	Q. Well, that would be just if the individual	22	women were going to have complications that would lead	
23	doctor running the session talked about it?	23	to surgeons operating on those women to try to remove	
24	A. I don't know.	24	some or all of the mesh; they knew that would happen	
25	Q. Right? You don't know whether that was	25	to some number of women, correct?	
25	Q. Right: 10d don't know whether that was	23	to some number of women, correct:	
	Page 263		Page 2	265
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	Page 266		Page 2
1	Prolift® mesh, not only due to exposures but also due	1	Q. And from everything you've seen, did Ethicon
2	to other complications? Do you have an assumption one	2	make any effort at all to try to study the subject of
3	way or the other?	3	what is the best way, if there is one, or what is the
4	A. I have an assumption that they probably	4	safe way, if there is one, to remove some or all of
5	think that would be a possibility.	5	the Prolift® mesh when that is called for due to
6	Q. It was certainly foreseeable, right?	6	complications?
7	MR. SNELL: Objection, form. Go ahead.	7	MR. SNELL: Objection, form. Go ahead.
8	THE WITNESS: I think to a certain	8	THE WITNESS: I'm not an employee of
9	extent it's foreseeable that if you're putting a	9	Ethicon. I do not know what they knew. I have not
10	permanent material in someone that at some point that	10	come across any documents so far that I have reviewed
11	might have to come out.	11	that suggest one way or the other.
12	BY MR. SLATER:	12	BY MR. SLATER:
13	Q. And if you and if rephrase.	13	Q. Do you have an opinion one way or the other
14	And since that was foreseeable to Ethicon,	14	as to whether or not Ethicon should have at least
15	you would agree with me that Ethicon should have taken	15	studied the question and tried to come rephrase.
16	into account, well, what can we tell surgeons about	16	Do you have any opinion as to whether or not
17	how to deal with that situation if they do need to try	17	Ethicon should have studied that question and tried to
18	to remove some or all of the mesh; wouldn't that be a	18	do the best they could to give some information to
19	reasonable thing for Ethicon to think about?	19	surgeons on that issue?
20	A. There's where I sort of disagree with you	20	A. Prior to launching it?
21	because I think that any pelvic reconstructive surgeon	21	Q. Yes.
22	realizes that if they do surgery on someone,	22	A. No.
23	particularly if they're using permanent materials like	23	MR. SLATER: Take a break for a couple
24	permanent sutures, that they may have to go back in	24	minutes.
25	and take them out.	25	THE VIDEOGRAPHER: Going off the
	Page 267	+	Page 2
1			
1	O. Well, my question is did Ethicon have an	1	record, the time is 3:59 p.m.
1 2	Q. Well, my question is did Ethicon have an obligation, in your opinion, to try to accumulate		record, the time is 3:59 p.m. (Brief recess.)
2	obligation, in your opinion, to try to accumulate	2	(Brief recess.)
2	obligation, in your opinion, to try to accumulate information through study, through all of the	2 3	(Brief recess.) THE VIDEOGRAPHER: We're back on the
2 3 4	obligation, in your opinion, to try to accumulate information through study, through all of the resources available to Ethicon so that Ethicon could	2 3 4	(Brief recess.) THE VIDEOGRAPHER: We're back on the record. Here marks the beginning of Volume 1 of Tape
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2 3 4 5 6	obligation, in your opinion, to try to accumulate information through study, through all of the resources available to Ethicon so that Ethicon could give some guidance to surgeons and say, look, we're selling you this Prolift® to put in patients' bodies.	2 3 4 5 6	(Brief recess.) THE VIDEOGRAPHER: We're back on the record. Here marks the beginning of Volume 1 of Tape Number 5 of the deposition of Dr. Miles Murphy. The time is 4:18 p.m.
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Page 270 Page 272 1 a complication I could. 1 very difficult in many cases to remove portions of the Q. Well, let's talk about a woman who has 2 mesh, correct? 3 chronic pain and the mesh is fully integrated, the 3 MR. SNELL: Objection, form. 4 fibrosis has formed, so the mesh is fully integrated THE WITNESS: That would assume that 4 into the woman's pelvis. one was surmising that the mesh was the cause, which 5 Do you need more information than that? 6 in your case, if that's what you're saying, then, yes, 6 7 A. And what do you want me to remove? that would be a difficult thing to know what to do 8 Q. Well, I don't know. That's what I'm asking with. you, maybe part --BY MR. SLATER: 9 Q. Go to the next page of Exhibit 2002. New 10 A. I'm sorry. 10 11 Q. Part of the question is I suppose being able question, in Exhibit 2002, let's look at the third 11 12 to identify what you need to remove, right? page talking about this potential RCT. It talks at A. Well, your question implies that her pain is the top about other opinions, and this is a carryover, 13 13 being caused by the mesh being there, which I disagree I guess, from the prior pages where it says Trial 15 with that premise. Design Advice. Vincent Lucente says "speak to David 16 Q. It was my hypothetical. Grimes, California," then other under Other Opinions A. Okay. I didn't realize we were talking he names some other physicians. 17 18 hypothetical. 18 Do you see that? 19 Q. I'm giving you a hypothetical situation 19 A. Yes. 20 where a woman has a total Prolift® implant, and she is Q. What is the purpose of listing these other 20 suffering as a result of the implant from dyspareunia. opinions as dissenting voices. What does that mean? 21 The mesh has become very stiff all around the vagina A. Where is it -- oh, dissenting voices. I 22 think it's speaking to -- well, if you're going to and is causing her pain. 24 A. Okay, well, I began -design a trial, you'd like it to be unbiased. All the 25 MR. SNELL: Objection, form. You science we try and do, we try and minimize our bias. Page 271 Page 273 1 It's impossible to get rid of bias all together. So 1 can... 2 2 if you're going to design it and you happen to be a THE WITNESS: I began my answer -- I 3 company that makes one device that's going to be one 3 mean this cycle of questions by saying that I think to 4 suggest that one can be certain that you've removed 4 arm of the trial, it might be wise if you're going to 5 every single piece of mesh from someone who has had a go ahead with that trial to talk to people who might 6 total Prolift® is not something that you could assure have different biases. They may bring to the table yourself that you've done. Therefore, if you remove that they think mesh is a horrible idea, and maybe 8 some and the person still says they have pain and they they could inform you on how to do your randomized 8 can still then attribute that pain to the mesh, that trial. 9 9 doesn't mean it's true, and that could potentially 1.0 Q. So am I reading this correctly that as part 10 11 mean that she'd have surgery after surgery where of the discussion on February 2, 2006 about a 11 potential Prolift® RCT, the group of people that were people took out small amounts of mesh expecting that 13 that's going to make her pain better, when that had there, including yourself, discussed bringing in nothing to do with her pain whatsoever in the first surgeons other than yourselves who were pro Prolift® 15 place. to say -- to bring others in who might not be so pro 16 BY MR. SLATER: the Prolift® to give input into the study design? Q. One of the problems when there is a Prolift® A. I don't recall this conversation. It was 17 17 18 in a woman's body and she is suffering from chronic six years ago, but by VL, Vince Lucente, saying be a 18 pelvic pain following the surgery that she didn't have better dissenting descenting voice, that implies that at least somewhere here you'd want someone with a before the surgery is pinpointing exactly what it is 20 that's generating the pain in many cases, correct? 21 dissenting voice. 21 Q. And the people that were discussed in that 22 A. Correct. 2.2 23 Q. The presence of the mesh within the woman's 23 context, the first one Linda Cardozo, do you know who pelvis complicates things to some extent because to 24 she is? A. I do. 25 the extent that you surmise that it's the mesh, it's 25

	Confidential - Subject to Stipul	acı	on and order or confractionary	
	Page 274		Page 27	76
1	Q. She's a surgeon, correct?	1	proficient with the Prolift®?	
2	A. Correct.	2	A. I think that what that was referring to was	
3	Q. Is she in United Kingdom?	3	if you're doing a randomized trial, abdominal	
4	A. Yes.	4	sacrocolpopexy versus this, chances are most of the	
5	Q. Very well respected?	5	people that you're going to be getting to be surgeons	
6	A. Yes.	6	will have done a lot more abdominal sacrocolpopexy,	
7	Q. Then it says avoid Linda Brubacher. Do you	7	when it would present bias into the study if you had	
8	know why that is stated?	8	someone who had done 300 abdominal sacrocolpopexies	
9	A. I don't know why.	9	and had only done one Prolift®.	
10	Q. And then according to this, Vince Lucente	10	Q. Meaning that you wanted to have a solid base	
11		11		
12	Do you see that?	12	curve wouldn't become a factor influencing outcomes?	
13	A. I do.	13	A. Correct.	
14	Q. Do you know why he said that?	14	MR. SLATER: I'm going to mark a	
15	A. Maybe because I know that she had done a	15		
	randomized, controlled trial before in reconstructive	16	(Document marked for identification	
16	pelvic surgery.		as Murphy Deposition Exhibit No. 3.)	
17		17		
18	Q. So during this meeting regarding a potential	18	BY MR. SLATER:	
19	Prolift® RCT, this meeting taking place in February of	19	Q. This was an advisory board that took place	
20	2006, it was suggested that Anne Weber would be	20	March 21 and 22, 2006, and it states that you were one	
21	potentially a good person to bring in to have input	21	of the members of that advisory board that was	
22	into the study design?	22	•	
23	A. One can surmise that from this, yes.	23	Do you see that?	
24	Q. Let me ask you to back up for a second.	24	A. Correct.	
25	Unrelated question but related to Linda Cardozo.	25	Q. If you could, turn to there's Bates	
	Page 275		Page 27	77
1				77
1 2	Did you see any documentation with regard to	1	numbers at the bottom. The last three digits are 962.	77
2	Did you see any documentation with regard to Linda Cardozo's viewpoint on the Prolift® in your	1 2	numbers at the bottom. The last three digits are 962. In the middle of the page it says	77
2 3	Did you see any documentation with regard to Linda Cardozo's viewpoint on the Prolift® in your review of materials in this case?	1 2 3	numbers at the bottom. The last three digits are 962. In the middle of the page it says "Discussion Point 4: Is Gynemesh® PS the mesh of	77
2 3 4	Did you see any documentation with regard to Linda Cardozo's viewpoint on the Prolift® in your review of materials in this case? A. I don't recall seeing that.	1 2 3 4	numbers at the bottom. The last three digits are 962. In the middle of the page it says "Discussion Point 4: Is Gynemesh® PS the mesh of choice?"	77
2 3 4 5	Did you see any documentation with regard to Linda Cardozo's viewpoint on the Prolift® in your review of materials in this case? A. I don't recall seeing that. Q. Is she someone you know personally, or you	1 2 3 4 5	numbers at the bottom. The last three digits are 962. In the middle of the page it says "Discussion Point 4: Is Gynemesh® PS the mesh of choice?" Do you see where I'm reading?	77
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			on and order of confidentiality
	Page 278		Page 280
1	misstate.	1	Q. So according to this document, that was a
2	MR. SLATER: You think I misstate?	2	suggestion that Dr. Lucente made, which was if we
3	What's your objection?	3	start out with Gynemesh® PS but a better mesh comes
4	THE WITNESS: I don't see it.	4	along, can we switch in the middle?
5	MR. SNELL: You said it was a	5	A. He says to consider that, yes.
6	suggestion. It's actually a discussion point.	6	Q. Okay. And then just below that, according
7	BY MR. SLATER:	7	•
8	Q. Let me ask you, do you remember this	8	A. Could be Marcus Carey, that's a name that I
9	meeting?	9	know, but I don't know if he was there or not. I
10	A. I remember it vaguely.	10	think he's a UK urogynecologist.
11	Q. These discussion points are summaries of	11	Q. According to whoever MC is, it says,
12	different points in the discussion that took place at	12	"Recruitment must be complete in no more than 1 year
13	that advisory board, correct?	13	because of potential redundancy of study by the time
14	A. Sounds reasonable.	14	of publication due to anticipated superior products."
15	Q. And Discussion Point 4 the topic listed as	15	So somebody during this meeting also pointed
16	one of the things that was discussed is the subject of	16	out that there was an expectation that something
17	"is Gynemesh® PS the mesh of choice," correct?	17	superior was going to be coming out, so if you were
18	A. That's the title of it, yes.	18	going to start, we need to get started basically,
19	Q. And then the text right under that starts	19	right?
20	out by saying, "If a lighter, softer mesh were	20	MR. SNELL: Objection, form.
21	available for the trial at the time it is due to start	21	THE WITNESS: I mean, I'm reading what
22	then this might be the preferred option."	22	I'm I mean
23	That's the first part of what it states,	23	BY MR. SLATER:
24	correct?	24	Q. You don't recall one way or the other?
25	A. That's what it states, yes.	25	A. Yeah, I don't recall one way or the other.
		1	
	Page 279		Page 281
1	Page 279 O. Do you recall a discussion at this meeting	1	Page 281 O. Let's go to the next statement. According
1 2	Q. Do you recall a discussion at this meeting	1 2	Q. Let's go to the next statement. According
2	Q. Do you recall a discussion at this meeting with regard to the question of whether Gynemesh® PS	1 2 3	
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	Confidential - Subject to St		. С 1 \		
		Page 282		Pag	ge 284
1	Q you agreed with that decision?		1	saying I mean, are you saying the advisory board	
2	A. No.		2	wasn't trying to have as good a study as possible?	
3	Q. According to this document, that was what		3	A. Well, I'm saying that you had just asked	
4	was agreed on behalf of the advisory board, correct?		4	me previously about MC's comments that you want to be	
5	A. According to this statement right here, he's		5	complete in one year because of potential redundancy.	
6	saying that, yes. I haven't had a chance to read		6	So what happens is and Anne Weber complains about	
7	through the rest of it.		7	this all the time, that you study something, and by	
8	Q. According to this document, it was agreed at		8	the time you study it, people have changed how they do	
9	this Prolift® advisory board that was discussing the		9	it, and now the study doesn't mean as much. So for	
10	structuring of an RCT to test the Prolift® against an		10	reasons like you were saying earlier, you know, you	
11	alternative procedure that as long as each of the		11	want to have data whenever possible, so you sometime	
12	surgeons had performed at least ten Prolifts® with at		12	have to make compromises.	
13	least five of them being anterior Prolifts®, that		13	Q. Okay. Ten procedures at minimum was the	
14	would be sufficient, correct?		14		
15	That's what it states in the document,		15	A. If you say so. I don't recall exactly.	
16	,		16	Q. You're not sure one way or the other?	
17	MR. SNELL: Objection, form.		17	A. I know it was somewhere I know it I	
18	THE WITNESS: Exactly. It's what it		18	thought it was a pretty low number.	
19	states right there.		19	Q. Let's go to the Discussion Point 4. Let's	
	BY MR. SLATER:			come back to the post-meeting note now.	
20	Q. Do you recall one way or the other whether		20	A. Okay.	
21	•		21	·	
	you agreed or disagreed with that?		22	Q. The post-meeting note states, after	
23	A. I can anticipate that I would have let me		23	consultation within Johnson & Johnson, a decision has	
24			24	been reached to proceed with the current mesh.	
25	number to all to then be saying that someone who		25	Gynemesh	
]	Page 283		Pag	ge 285
1	has done years and years of doing an abdominal	Page 283	1	Pag A. I'm sorry. I'm missing where you are.	ge 285
1 2		Page 283	1 2		ge 285
	has done years and years of doing an abdominal	Page 283		A. I'm sorry. I'm missing where you are.	ge 285
2	has done years and years of doing an abdominal sacrocolpopexy, that then comparing it to someone who	Page 283	2	A. I'm sorry. I'm missing where you are.Q. On the page with the 62 at the bottom.	ge 285
2 3	has done years and years of doing an abdominal sacrocolpopexy, that then comparing it to someone who has only done ten Prolifts®, I would think that that	Page 283	2	A. I'm sorry. I'm missing where you are.Q. On the page with the 62 at the bottom.A. I'm on it, that page. I just don't see	ge 285
2 3 4	has done years and years of doing an abdominal sacrocolpopexy, that then comparing it to someone who has only done ten Prolifts®, I would think that that would introduce significant bias into the results of	Page 283	2 3 4	A. I'm sorry. I'm missing where you are.Q. On the page with the 62 at the bottom.A. I'm on it, that page. I just don't see where you are.	ge 285
2 3 4 5	has done years and years of doing an abdominal sacrocolpopexy, that then comparing it to someone who has only done ten Prolifts®, I would think that that would introduce significant bias into the results of the study.	Page 283	2 3 4 5	 A. I'm sorry. I'm missing where you are. Q. On the page with the 62 at the bottom. A. I'm on it, that page. I just don't see where you are. Q. Under Discussion Point 4. 	ge 285
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			on and order or confractional	
	Page 286			Page 288
1	A. I do.	1	A. No.	
2	Q. And it states, after consultation within	2	Q. Did you know at that point in time that the	
3	Johnson & Johnson, a decision has been reached to	3	expectation was that the Prolift+M® would be a better	
4	proceed with the current mesh. Gynemesh® PS is the	4	alternative for younger, sexually active women?	
5	mesh within the approved Prolift® System.	5	A. Did I know it?	
6	You see that?	6	Q. Did you know that that was the expectation,	
7	A. I do.	7	or was that the expectation?	
8	Q. So according to this, Johnson & Johnson had	8	MR. SNELL: Objection, form.	
9	made the decision let's study Gynemesh® PS. We're not	9	THE WITNESS: At this time in 200	
10	going to do this, even if there is a lighter, softer	10	BY MR. SLATER:	
11	mesh available that might be the preferred option,	11	Q. No, before the Prolift+M® came out when	
12	we're going to use Gynemesh® PS, correct?	12	Dr. Lucente was new question.	
13	MR. SNELL: Object to form. Go ahead.	13	During the time period when Dr. Lucente was	
14	THE WITNESS: Correct.	14	holding patients back who were young and sexually	
15	BY MR. SLATER:	15	active waiting for the Prolift+M®, did you have an	
16	Q. I'm going to hand you a document we've	16	understanding of what the expectations were for the	
17	marked as Exhibit 240. This is an e-mail dated	17	Prolift+M® in terms of why he would do that?	
18	December 15, 2008 which attaches to it the transcript	18	MR. SNELL: Objection, form.	
19	of a webinar involving Dr. Lucente. And it's with	19	THE WITNESS: I can read from this that	
20	regard to the Prolift+M®, and if you could, turn to	20	his expectation was it would provide better sexual	
21	the first page of the actual webinar. There is a 56	21	function. I don't know what J&J's or Gynecare's	
22	at the bottom.	22	expectations were.	
23	There's a long paragraph from Dr. Lucente	23	BY MR. SLATER:	
24	responding to a question, the question being "did the	24	Q. Do you recall what your expectations were at	
25	change in graft properties of Prolift+M® require you	25	that time?	
	Page 287			Page 289
1	Page 287	1	A I didn't have expectations	Page 289
	to adjust your Prolift® technique in any way, if so	1 2	A. I didn't have expectations.	Page 289
2	to adjust your Prolift® technique in any way, if so where or how?"	2	Q. Go to the next page. Towards the bottom	Page 289
2 3	to adjust your Prolift® technique in any way, if so where or how?" Do you see where I am?	2 3	Q. Go to the next page. Towards the bottom there's a question, with less scar tissue formation,	Page 289
2 3 4	to adjust your Prolift® technique in any way, if so where or how?" Do you see where I am? A. Yes.	3 4	Q. Go to the next page. Towards the bottom there's a question, with less scar tissue formation, are you seeing less tissue	Page 289
2 3 4 5	to adjust your Prolift® technique in any way, if so where or how?" Do you see where I am? A. Yes. Q. I'm not going to read the whole entire long	2 3 4 5	Q. Go to the next page. Towards the bottom there's a question, with less scar tissue formation, are you seeing less tissue A. I'm sorry. Where are you?	Page 289
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	Daga 200	T		
	Page 290			Page 292
	talks about as traction banding or scarring?	1	THE WITNESS: According to what he	
2	MR. SNELL: Objection, form.	2	states here, I think that's a fair representation.	
3	THE WITNESS: Can we take them one at a	3	BY MR. SLATER:	
4	time?	4	Q. Do you recall being his partner at the time?	
5	BY MR. SLATER:	5	A. I do.	
6	Q. Sure.	6	Q. Do you recall that that's what he was	
7	A. So the first thing you had said was less	7	relating to you, that he was feeling that less?	
8	scar formation, I did not notice less scar formation.	8	A. I don't recall him specifically talking	
9	The next one was traction banding, is that	9	about traction bands or scar plate formation. I	
10	what you're asking?	10	remember him getting the sense that when he examined	
11	Q. Yes.	11	those patients, it felt even softer in the vagina.	
12	A. I don't recall noting less traction banding.	12	Q. Were you having the same experience when you	
13	Q. Did you know that Dr. Lucente was telling	13	started using the Prolift+M®, that you felt that the	
14	people that not only him but we are seeing less scar	14	mesh felt softer through the vagina?	
15	tissue formation and less tissue retraction with the	15	A. I can't say that I necessarily did feel	
	Prolift+M®?	16		
17	A. It doesn't surprise me that he said that.	17	Q. Go to the next page. Dr. Lucente is talking	
18	Q. When you say it doesn't surprise you, why	18	about in responding to a question where he was asked	
	not?	19	are there any patients in whom you would not use	
	A. Because I think reading what he said here		Prolift+M®, and he says, in our literature a little	
20		20	• •	
21	seems to be an accurate representation of the opinion	21	further down from the top he says, in our literature,	
22	he had at that time.	22	in our series points to the three areas that increase	
23	Q. Did you have the same opinion?	23	the likelihood of pain, and that is a patient of a	
24	A. I wouldn't say one way or the other. Again,	24	younger age, and I'm going to paraphrase a little,	
25	we have to see what time this was. I tend to be, for	25	second, a patient who has had a prior pelvic surgery	
	Page 291			Page 293
1		1	with a permanent material being utilized, whether	Page 293
	lack of a better term, a little bit more hard core	1 2	•	Page 293
2	lack of a better term, a little bit more hard core data driven than Dr. Lucente.	2	suture or graft, and, third, chronic pain disorder of	Page 293
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-1	Page 294		O. D. voor house one her orded as a standard Winsont	Page 29
1	disorders, but we've actually seen with any chronic	1	Q. Do you have any knowledge as to when Vincent	
2	pain," and he says he calls them relative	2	Lucente recalls having communicated that concern to	
3	contraindications.	3	Ethicon, in discussing it with people in medical	
4	Do you see that?	4	affairs at Ethicon?	
5	A. Yes.	5	A. I do not.	
6	Q. And in his practice he's representing that	6	Q. You would certainly agree with me that once	
7	he considered people with any sort of a chronic pain	7	Ethicon was aware of that concern, it's certainly	
8	history to have a relative start over.	8	something they should have taken into account in what	
9	In this webinar Dr. Lucente is stating here	9	warnings they were giving to surgeons and what	
.0	on the page that has the 58 at the bottom that in his	10	information they were giving to patients, correct?	
1	practice, patients with chronic pain, to his	11	MR. SNELL: Objection, form.	
2	perspective, had a relative contraindication to the	12	THE WITNESS: Not necessarily.	
3	Prolift® due to activation of the C-fibers.	13	BY MR. SLATER:	
4	Do you see that?	14	Q. Well, it's certainly something they should	
5	MR. SNELL: Objection, form.	15	have taken into account, right?	
6	THE WITNESS: I see that.	16	MR. SNELL: Objection, form.	
7	BY MR. SLATER:	17	THE WITNESS: Taken into account in	
8	Q. Do you recall from working with him that	18	what regard?	
9	that was his practice?	19	BY MR. SLATER:	
0	A. I recall there came a time where he sort of	20	Q. Ethicon has an obligation to warn of the	
1		21	potential risks in connection with the use of the	
2	Q. Did you feel that way?	22	Prolift®, which include would include someone who	
3	A. I felt like I think we already went over	23	has a relative contraindication that could increase	
	this, that in patients with chronic pain syndromes, I			
4	• •	24	their risk, right?	
15	really only felt chronic pelvic pain well, yeah,	25	MR. SNELL: Objection, form. You're	
	Page 295			Page 29
1	let's just go back to chronic pain syndromes, that in	1	misstating now.	
2	general, operating on those people is going to	2	MR. SLATER: I am?	
3	increase their risk of more postoperative pain than	3	MR. SNELL: Yes.	
4	the average person, in that it might be wise to think	4	MR. SLATER: I'll ask a new question.	
5	4		*	
c	twice about putting permanent materials in those	5	MR. SNELL: He is talking liability.	
6	patients.		MR. SNELL: He is talking liability. You're talking medical contraindications.	
6 7				
	patients. Q. Do you know when it was that Ethicon first	6	You're talking medical contraindications. MR. SLATER: I don't know what you're	
7 8	patients. Q. Do you know when it was that Ethicon first became aware of that viewpoint, that there were	6	You're talking medical contraindications. MR. SLATER: I don't know what you're talking about.	
7 8 9	patients. Q. Do you know when it was that Ethicon first became aware of that viewpoint, that there were surgeons in your group with Dr. Lucente thought this	6 7 8 9	You're talking medical contraindications. MR. SLATER: I don't know what you're talking about. BY MR. SLATER:	
7 8 9	patients. Q. Do you know when it was that Ethicon first became aware of that viewpoint, that there were surgeons in your group with Dr. Lucente thought this way or that any other surgeons out there thought that	6 7 8 9	You're talking medical contraindications. MR. SLATER: I don't know what you're talking about. BY MR. SLATER: Q. Did Ethicon have an obligation to warn	
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		age 298			Page 300
	question. I'm not asking it with particular to pain			obligation to do something to follow up on that?	
2	conditions right now, okay. Here's my question, clean		2	MR. SNELL: Objection, form.	
3	question: If Ethicon became aware of a certain		3	THE WITNESS: To do something to follow	
4	patient criteria, something about the patient's			ip. I think maybe it's reasonable to do something to	
5	background that could increase the patient's risk to			ook at it in some way.	
6	have a poor outcome, for example, to cause the patient			BY MR. SLATER:	
7	to develop more pain after the Prolift® than other		7	Q. And if people in Ethicon concluded that	
8	patients, if Ethicon was aware of that, did they have			here was a higher potential risk for pain for	
9	an obligation, first of all, to look into it and study			patients if they already had a chronic pain condition	
10	it to determine whether it needed to be communicated			and were to have a Prolift® put in their body, if	
11	to patients and physicians?			Ethicon had enough information to believe this is not	
12	MR. SNELL: Objection, form. Go ahead.			some remote possibility but we have information that	
13	THE WITNESS: No.			we think is reliable, did they have an obligation to	
14	BY MR. SLATER:		14 v	warn about that?	
15	Q. So it would be okay for Ethicon to receive		15	MR. SNELL: Objection, form.	
16	such information and to do nothing about it, not think		16	THE WITNESS: I'm not trying to be	
17	about it, not study the question and to just move on?			argumentative, but you're always talking about just	
18	A. I didn't say that.			Prolift®, and it assumes that that's sort of the only	
19	Q. That was what my question was, and you said			way one can treat prolapse. And if you think that	
20	no, so I just want you to know that's what you said.			people with prolapse should be able to have the choice	
21	MR. SNELL: Now you're misstating his		21 t	to be treated, then you have to look at the options	
22	answer.			for treatment.	
23	THE WITNESS: If we could read back		23 I	BY MR. SLATER:	
24	those two things		24	Q. Do you understand that a medical device	
25	MR. SNELL: Read both questions.		25 ı	manufacturer like Ethicon has an obligation to warn	
	p _e	age 299			Page 301
	1.	uge 2))			1 450 301
1	THE WITNESS: I'm quite sure they	uge 2))	1 8	about the contraindications, the warnings, the risks,	ruge 301
1 2		uge 277		about the contraindications, the warnings, the risks, he adverse events associated with that product	1 ugo 301
	THE WITNESS: I'm quite sure they	uge 277	2 t	· ·	Tuge 301
2	THE WITNESS: I'm quite sure they would say different things.	go 277	2 t	he adverse events associated with that product	rage sor
2 3 4	THE WITNESS: I'm quite sure they would say different things. MR. SLATER: We don't need to read both	ge 277	2 t	he adverse events associated with that product because they're selling that system? Do you	rage sor
2 3 4	THE WITNESS: I'm quite sure they would say different things. MR. SLATER: We don't need to read both questions, okay, Burt, with all due respect. I'm not	.gc 2//	2 t 3 t 4 t 5	the adverse events associated with that product because they're selling that system? Do you understand that that's an obligation?	Tugo sor
2 3 4 5	THE WITNESS: I'm quite sure they would say different things. MR. SLATER: We don't need to read both questions, okay, Burt, with all due respect. I'm not going to waste ten minutes.	.gc 2//	2 t 3 t 4 t 5	the adverse events associated with that product because they're selling that system? Do you understand that that's an obligation? A. Do I understand it's an obligation from a	Tuge 301
2 3 4 5 6	THE WITNESS: I'm quite sure they would say different things. MR. SLATER: We don't need to read both questions, okay, Burt, with all due respect. I'm not going to waste ten minutes. BY MR. SLATER:	gc 277	2 t 3 t 4 t 5 6 t	the adverse events associated with that product because they're selling that system? Do you understand that that's an obligation? A. Do I understand it's an obligation from a regulatory standpoint?	Tuge 301
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	n out
13 late 2005 or early 2006 that he felt that chronic pain 13 potential issue?	
14 was a relative contraindication to the use of the 14 MR. SNELL: Objection, form.	
L5 Prolift® in patients, if he provided that information 15 THE WITNESS: I don't see that there	
6 to Ethicon at that time, did Ethicon have an 16 could be much downside to it. In fact, I think	
17 obligation to get that information out to physicians 27 well, you're probably going to strike it if I say	
18 so that they would have that information when 18 anything else.	
19 considering whether or not to recommend a Prolift® to 19 MR. SNELL: Give your full answer. He	
20 patients? 20 can strike whatever. I'll ask it later.	
MR. SNELL: Objection, form. Go ahead. 21 THE WITNESS: I think in one of what w	/e
THE WITNESS: I respect Dr. Lucente's 22 call throw-away journals, a journal that is not a	
23 opinions very much. Do I think that Ethicon was 23 peer-reviewed journal, he states that pretty clearly,	
24 obligated to do anything just because he had an 24 and I think that was somewhere around 2007/2008.	
25 opinion? No. 25 MR. SLATER: I'm going to move to	
25 VIII. SELVIER. This going to move to	
Page 303	Page 305
1 BY MR. SLATER: 1 strike that last part. It's too late in the day for	
2 Q. What did Ethicon need to do as soon as 2 me to try to think anything through.	
3 Vincent Lucente provided that information to them? 3 BY MR. SLATER	
4 Let's assume it happened in late 2005, early 2006. 4 Q. Can you turn to the page with the 61 at the	
5 What was Ethicon's obligation at that point? 5 bottom.	
6 A. I think to continue to monitor the ongoing 6 A. The same document?	
7 studies of TVM and Prolift® to see if that actually 7 Q. Same document.	
8 seemed to be the case. 8 There is a discussion at the top between	
9 Q. And for how long would they would 9 Dr. Lucente and Douglas Greer.	
10 Ethicon reason rephrase. 10 You know Douglas Greer?	
And how long would it be reasonable for 11 A. I do not.	
2 Ethicon to continue to monitor that issue while 12 Q. Do you know who he is?	
13 Prolifts® continued to be put in women's bodies every 13 A. Not to my recollection.	
14 day, including women with chronic pain conditions? 14 Q. He is talking about, coming back from the	
L5 A. I think it's I think once that there was 15 prior page, some issues about potential infection	
16 data from at least more than one study that showed 16 rephrase. I'm going to withdraw that.	
17 At the top of the page with the 61, Douglas	
	ncent
18 higher in people with pre-existing chronic pain 19 Greer makes a point where in a discussion with Vir	
	798
19 conditions than in those who did not have pre-existing 19 Lucente here under the context of vaginal	as
19 conditions than in those who did not have pre-existing 20 chronic pain conditions. 19 Lucente here under the context of vaginal 20 rehabilitation, do you see that's what Dr. Lucente w	
19 conditions than in those who did not have pre-existing 20 chronic pain conditions. 21 Q. Was that data ever available? 22 Indicate the context of vaginal 20 rehabilitation, do you see that's what Dr. Lucente was 21 discussing?	
19 conditions than in those who did not have pre-existing 20 chronic pain conditions. 21 Q. Was that data ever available? 22 A. I have never seen a study that shows that 29 Lucente here under the context of vaginal 20 rehabilitation, do you see that's what Dr. Lucente was discussing? 21 discussing? 22 A. No.	
19 conditions than in those who did not have pre-existing 20 chronic pain conditions. 21 Q. Was that data ever available? 22 A. I have never seen a study that shows that 23 comparison that I'm aware of. 29 Lucente here under the context of vaginal 20 rehabilitation, do you see that's what Dr. Lucente w 21 discussing? 22 A. No. 23 Q. Second line of the page.	
19 conditions than in those who did not have pre-existing 20 chronic pain conditions. 21 Q. Was that data ever available? 22 A. I have never seen a study that shows that 29 Lucente here under the context of vaginal 20 rehabilitation, do you see that's what Dr. Lucente was discussing? 21 discussing? 22 A. No.	

	Confidential - Subject to Sti				
		ge 306			Page 308
	other parts of the body in other fields have less		1	A. It's a society of a medical society of	
2	concern about splitting the incisions open when they			Gynecologic Surgeons that have particular interest in	
3	get the patients up and moving around and starting to			doing surgery on gynecologic patients.	
4	rehabilitate after surgery.		4	Q. This article was published in the journal	
5	Do you see that?			titled Obstetrics & Gynecology, correct?	
6	A. I do see that.		6	A. Correct.	
7	Q. And then Doug Greer says their incisions		7	Q. And the publication date is November 2008,	
8	don't live in a sea of bacteria.			correct?	
9	Do you see that?		9	A. Correct.	
10	A. I see that.		.0	Q. And it says, the objective of this article	
11	Q. He's referring to the environment of the			is to set forth what you found or what you	
12	vagina, correct?			determined rephrase.	
13	A. Dr. Greer or Douglas Greer, yes, I would		.3	The objective of this study is defined in	
14	think.			the abstract portion as "to develop guidelines	
15	Q. And then Dr. Lucente responds, absolutely,			regarding whether graft or native tissue repair should	
16	agreeing with that as being an issue, correct?			be done in transvaginal repair of anterior, posterior	
17	MR. SNELL: Objection, form.			or apical pelvic organ prolapse," correct?	
18	THE WITNESS: He states absolutely.		.8	A. Correct.	
19	BY MR. SLATER:		.9	Q. And this was a study that you did along with	
20	Q. It may not be the terminology you would			some other physicians to try to meet that objective,	
21	choose, but you would agree that the environment of			correct?	
22	the vagina is a sea of bacteria, correct?		22	A. It was a systematic review, and from the	
23	MR. SNELL: Objection, form.			systematic review, we developed guidelines. True	
24	THE WITNESS: There is a great deal of			sense of the word, it wasn't a study, like an	
25	bacteria in the vagina. There's a great deal of	2	25 6	experimental study.	
	Pa	ge 307			Page 309
		6			1 age 307
1	bacteria on the skin, but more so in the vagina than		1	Q. Let's go through some of the findings that	1 age 307
1 2					rage 507
	bacteria on the skin, but more so in the vagina than		2 8	Q. Let's go through some of the findings that	Tage 307
2	bacteria on the skin, but more so in the vagina than on the skin.		2 a 3 l	Q. Let's go through some of the findings that are in this article. Let's look at the Materials and	rage 507
2	bacteria on the skin, but more so in the vagina than on the skin. BY MR. SLATER:		2 a 3 l 4 s	Q. Let's go through some of the findings that are in this article. Let's look at the Materials and Methods section actually first. Right under that it	Tage 307
2 3 4	bacteria on the skin, but more so in the vagina than on the skin. BY MR. SLATER: Q. Can the bacteria in the vagina traverse		2 a 3 l 4 s 5 l	Q. Let's go through some of the findings that are in this article. Let's look at the Materials and Methods section actually first. Right under that it says, the Society of Gynecologic Surgeons is a select	1 age 307
2 3 4 5	bacteria on the skin, but more so in the vagina than on the skin. BY MR. SLATER: Q. Can the bacteria in the vagina traverse through the incision after Prolift® surgery,		2 3 1 4 5 5 1 6 l	Q. Let's go through some of the findings that are in this article. Let's look at the Materials and Methods section actually first. Right under that it says, the Society of Gynecologic Surgeons is a select member group of more than 250 physicians representing	1 age 307
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		T	on and order or confractional	
	Page 310			Page 312
1	Q. Let's start with the Results section on page	1	• •	
2	1125. About three-quarters of the way down in the	2	guidelines is to synthesize all a lot of data and	
3	right-hand column it states, start of the last	3	then suggest how people can proceed in their practice.	
4	paragraph, "from a historical perspective, native	4	Q. In this study and these recommendations	
5	tissue repair can be considered the default or	5	rephrase.	
6	standard of care."	6	And in this article there is a comparison of	
7	Do you see that?	7	nonabsorbable synthetic mesh or an analysis of	
8	A. I do.	8	nonabsorbable synthetic mesh; that's what is stated on	
9	Q. And when you refer to the default or	9	Page 1126, correct?	
10	standard of care, what are you saying?	10	A. Correct.	
11	A. It means that from a historical perspective,	11	Q. Towards the bottom of the page in the	
12	meaning in the past, all that was available were	12	right-hand column, "There is a paragraph that starts,	
13	native tissue repairs.	13	these studies found a number of complications	
14	Q. Go to the next page regarding "Synthetic	14	associated with the use of synthetic graft in the	
15	Graft Use in the Anterior Compartment."	15	anterior compartment."	
16	Do you see that?	16	Do you see that paragraph?	
17	A. I do.	17	A. I do.	
18	Q. And you indicate here the first randomized	18	Q. You then continued, "when considering these	
19	trial of use of this graft, and that was an absorbable	19	studies in conjunction with the case series of	
20	synthetic graft, with anterior colporrhaphy was	20	anterior compartment mesh use, the following adverse	
21	published in 2001 by Weber, et. al.	21	outcomes have been reported," and then you list	
22	That's a study that was published and is	22	"infection, hemorrhage, mesh erosion, dyspareunia,	
23	widely cited, correct?	23	incontinence, bladder injury, voiding dysfunction and	
24	A. Yes.	24	ureteric obstruction," correct?	
25	Q. And that was a study that focused on a	25	A. Correct.	
		_		
	Page 311			Page 313
1	comparison of this absorbable graft material versus	1	Q. You then indicate, "Overall, the rate of	Page 313
1 2	comparison of this absorbable graft material versus anterior colporrhaphy in terms of anatomic outcomes,	1 2	mesh erosion/exposure ranges from 0-24.5%," correct?	Page 313
	comparison of this absorbable graft material versus anterior colporrhaphy in terms of anatomic outcomes, correct?		mesh erosion/exposure ranges from 0-24.5%," correct? A. Correct.	Page 313
2 3 4	comparison of this absorbable graft material versus anterior colporrhaphy in terms of anatomic outcomes, correct? A. Yes, I believe there was a third arm as	2	mesh erosion/exposure ranges from 0-24.5%," correct? A. Correct. Q. Then you say, "In summary, there are	Page 313
2 3 4	comparison of this absorbable graft material versus anterior colporrhaphy in terms of anatomic outcomes, correct?	2 3	mesh erosion/exposure ranges from 0-24.5%," correct? A. Correct.	Page 313
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2 3 4 5 6	comparison of this absorbable graft material versus anterior colporrhaphy in terms of anatomic outcomes, correct? A. Yes, I believe there was a third arm as well, the ultra lateral anterior colporrhaphy. Q. And that study focused specifically on the	2 3 4 5 6	mesh erosion/exposure ranges from 0-24.5%," correct? A. Correct. Q. Then you say, "In summary, there are trade-offs between using nonabsorbable synthetic mesh or native tissue in anterior compartment repair,"	Page 313
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	Confidential - Subject to Stipula			
	Page 314			Page 316
1	section about the use of synthetic mesh for anterior	1	, , , ,	
2	repairs says, "It is suggested that nonabsorbable	2	A. I think that's what we were stating, yes.	
3	synthetic mesh may improve anatomic outcomes of	3	Q. You then state, "The risk of mesh	
4	anterior vaginal wall repair, but there are	4	erosion/exposure in the posterior compartment is	
5	significant trade-offs in regard to the risk of	5	nonexistent in native tissue repair."	
6	adverse events."	6	Why did you state that?	
7	Do you see that?	7	A. Because while it's something that's obvious,	
8	A. Yes.	8	we're still trying to point out to people that we're	
9	Q. That was certainly a statement that you	9	just stating the facts.	
10	believed was accurate as of the time you published	10	Q. You then state, "There are no comparative	
11	this article in November 2008, correct?	11	studies to guide any recommendation on the use of	
12	A. I believe it was accurate, but it is	12	nonabsorbable synthetic mesh in posterior vaginal wall	
13	important to realize that I published this on behalf	13	repair when compared with native tissue repair."	
14	of the whole group. It simply wasn't a reflection of	14	That was the conclusion, correct?	
15	my pure opinion, but, yes, I agreed with that.	15	A. That was our statement.	
16	Q. And you put your name on the article as the	16	Q. Then there's a section on multiple	
17	author, right?	17	compartment use, and you point out that there are no	
18	A. Absolutely.	18	randomized studies, correct?	
19	Q. You then say at the end "Weak," and that's	19	A. Correct.	
20	grading, what, the strength of the recommendation with	20	Q. Further down you point out in that same page	
21	regard to the use of graft material for anterior	21	on 1128 of this article, "The quality of the evidence	
22	repairs?	22	for the use of nonabsorbable synthetic grafts in	
23	A. That's stating that the recommendation is a	23	multiple compartments is graded as very low," correct?	
24	weak recommendation based on the fact that it's not	24	A. Correct.	
25	based on a whole lot of great data.	25	Q. And that was your viewpoint at the time,	
	Page 315	+		Page 317
1	- 10-1			rage 317
1	Q. So there is a lack of data that you felt was	1	correct?	rage 317
1 2		1 2	correct? A. Again, that's talking about the fact that	rage 317
	Q. So there is a lack of data that you felt was			rage 317
2	Q. So there is a lack of data that you felt was reliable to in this context at that point on that	2	A. Again, that's talking about the fact that	rage 317
2 3 4	Q. So there is a lack of data that you felt was reliable to in this context at that point on that question?	2 3	A. Again, that's talking about the fact that the quality of evidence is low because there's	rage 317
2 3 4	Q. So there is a lack of data that you felt was reliable to in this context at that point on that question? A. Yes, as there is in most pelvic	2 3 4	A. Again, that's talking about the fact that the quality of evidence is low because there's essentially no evidence.	rage 317
2 3 4 5 6	 Q. So there is a lack of data that you felt was reliable to in this context at that point on that question? A. Yes, as there is in most pelvic reconstructive surgery. 	2 3 4 5	A. Again, that's talking about the fact that the quality of evidence is low because there's essentially no evidence.Q. You then state, "The decision for grading	rage 317
2 3 4 5 6	 Q. So there is a lack of data that you felt was reliable to in this context at that point on that question? A. Yes, as there is in most pelvic reconstructive surgery. Q. Go to the next page. On Page 1127, 	2 3 4 5 6	A. Again, that's talking about the fact that the quality of evidence is low because there's essentially no evidence. Q. You then state, "The decision for grading was based on the fact that there are no comparative	rage 317
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. So there is a lack of data that you felt was reliable to in this context at that point on that question? A. Yes, as there is in most pelvic reconstructive surgery. Q. Go to the next page. On Page 1127, right-hand side, there is a paragraph with regard to use of nonabsorbable synthetic mesh in posterior vaginal wall repairs. Do you see that? A. Are we talking about nonabsorbable now? Q. Yes. A. Yes, I see the recommendation. Q. And you state, "The quality of the evidence for the use of nonabsorbable synthetic graft in the posterior wall is graded as very low." What did you mean by that? A. It means that there are not a lot of randomized trials looking at permanent synthetic mesh in the posterior compartment compared to native tissue repairs. Q. You then talk about, a little further down, "there are uncertain trade-offs with its use."	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Again, that's talking about the fact that the quality of evidence is low because there's essentially no evidence. Q. You then state, "The decision for grading was based on the fact that there are no comparative studies in the literature about the use of nonabsorbable synthetic grafts for the repair of combined anterior, posterior and/or apical compartment prolapse." Saying the same thing, there's no comparative studies in that subject, correct? A. Correct. Q. And as a result you say, "there are uncertain trade-offs with its use," right? A. Correct. Q. You then point out, the risk of graft erosion or exposure in the vagina is nonexistent in native tissue repair, correct? A. Yes. Q. At the top right there's a discussion of the 1999 National Institutes of Health workshop examining the state of basic epidemiologic and clinical research	rage 317

	Page 318			Page 320
1	that.	1	A. I'm on that page. I don't see the	
2	Do you see that?		recommendations. That's the start of	
3	A. I do.	3	Q. It's the heading on the left-hand side.	
4	Q. And that's a paper authored by Anne Weber	4	A. Oh, the heading, yes, I see it.	
5	and some other doctors titled the standardization of	5	Q. You started out by saying, "Balancing the	
6	terminology for researchers in female pelvic floor	6	potential risks and benefits of reconstructive surgery	
7	disorders.	7	always poses a challenge for pelvic surgeons. This is	
8	Do you see that?	8	particularly true for new procedures," right?	
	A. I do.	9	A. That's what I state.	
9	Q. And why did you cite to that meeting and to		Q. And that was your viewpoint at the time,	
10	that article?	10		
11	A. I'd have to read through this paragraph to	11 12	A. That was my viewpoint.	
	tell you why. Would you like me to do that?		Q. The new procedures would be, for example,	
13	• • •	13		
14	Q. Sure. It's short.	14		
15	A. (Witness reviews documents.) Okay. I've	15	A. That would be an example of a new procedure	
	read that paragraph. Would you mind repeating the	16	at that time.	
17	•	17	Q. You continue, "Vaginal repairs with native	
18	Q. Sure. Why did you cite to that meeting and	18	tissue have been performed for decades, and although	
19		19	there are questions about the durability of these	
20	A. The point of this section of the discussion	20	repairs, the risks are well-known. In particular,	
21	was to guide people in how to conduct future research	21	potential long-term sequelae are easier to predict	
22	on this topic and that since there was so little data	22	given the long track record of these procedures," and	
23	out there when we published this, we thought well who	23	that was a true statement, correct?	
24		24	A. That is a true statement. I would like to	
25	find anything, and so part of our goal in this paper	25	add something qualifying that.	
	Page 319			Page 321
1	Page 319 was to suggest how to best go about conducting future	1	Q. Well, when you made that statement, that's	Page 321
	•	1 2		Page 321
	was to suggest how to best go about conducting future			Page 321
2	was to suggest how to best go about conducting future research, and there were certain domains that we	2	what you published and felt to be a true statement,	Page 321
2 3 4	was to suggest how to best go about conducting future research, and there were certain domains that we thought should be covered, and the citation that I	2 3	what you published and felt to be a true statement, correct?	Page 321
2 3 4	was to suggest how to best go about conducting future research, and there were certain domains that we thought should be covered, and the citation that I cite goes along with some of the previous	2 3 4	what you published and felt to be a true statement, correct? A. Yes.	Page 321
2 3 4 5	was to suggest how to best go about conducting future research, and there were certain domains that we thought should be covered, and the citation that I cite goes along with some of the previous recommendations that were listed in that citation.	2 3 4 5	what you published and felt to be a true statement, correct? A. Yes. Q. You then continue, "Some studies show a decrease in recurrence of prolapse associated with use	Page 321
2 3 4 5 6	was to suggest how to best go about conducting future research, and there were certain domains that we thought should be covered, and the citation that I cite goes along with some of the previous recommendations that were listed in that citation. Q. So, in part, you're telling people who read	2 3 4 5 6	what you published and felt to be a true statement, correct? A. Yes. Q. You then continue, "Some studies show a decrease in recurrence of prolapse associated with use	Page 321
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	Page 322			Page 324
1	doctors.	1	<u>.</u>	
2	BY MR. SLATER:	2	benefits, and for some patients you choose native	
3	Q. Well, ultimately, you talked to doctors in	3	tissue repair over the use of the Prolift®, right?	
4	this context with the understanding that that will	4	A. Well, that's an excellent question. Do I	
5	help guide their decisions on what treatment to	5	choose it, or does the patient choose it? In my	
6	recommend to patients, correct?	6	practice, I tend to try to provide all the information	
7	A. Well, to a certain extent, but doctors have	7	that I can to a patient and work with her to come to a	
8	to then filter that with their own clinical	8	decision, and I say that because that's not always the	
9	experience.	9	way it was. I think 10, certainly 20 years ago, the	
10	Q. Well, that's what happens with every doctor	10	patient came in, the doctor said, you need this	
11	reading every article like this. They read it and	11	surgery, patient doesn't even know what was done to	
12	they filter it based on their own background and	12	their body.	
13	experience, right?	13	Q. As things stand now	
14	A. Yes. My point is that this article that	14	A. Yes.	
15	we're talking about, and you're quoting all these	15	Q and as things have stood throughout the	
16	things from, was geared to be read by physicians, not	16	time you have utilized the Prolift®, you make	
17	by patients.	17	recommendations to patients, you offer options, and	
18	Q. I never suggested it was.	18	then the patient makes the ultimate decision, correct?	
19	A. I thought that's what that last question	19	A. I would say it's a combination of the two.	
20	was, because you said about I'm recommending it to	20	I have some patients that it's totally their option.	
21	patients, when I'm really recommending to doctors.	21	Some patients they can't make the decision. They say,	
22	Q. What you're saying all right. I'll	22	Doctor, I'm not a doctor, you need to make that	
23	rephrase.	23	decision for me.	
24	What you're saying here with regard to the	24	Q. But even with those patients, you still	
25	paucity of randomized, comparative data to guide	25	offer them options, and then you just give the best	
	D 222			D 225
	Page 323			Page 325
1	recommendations regarding efficacy, you're talking	1		Page 325
1 2	recommendations regarding efficacy, you're talking about recommendations to other surgeons, or are you	2	likely to take your advice?	Page 325
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	Page 326			Page 328
	or uterosacral, or did you do both?	1	risk associated with the use of grafts about which	
2	A. I have a preference for uterosacral.	2	potential surgical candidates need to be counseled.	
	Q. And you also performed abdominal	3	The risk of erosion of grafts varies between studies,	
4	sacrocolpopexy on patients, correct?	4	but it is a risk that does not exist with native	
į	5 A. Correct.	5	tissue repairs."	
(Q. Both open and robotic?	6	You see what I just read?	
'	7 A. Correct.	7	A. I do.	
8	Q. And when I say "robotic," that would be	8	Q. You stand behind that, right?	
9	laparoscopic, correct?	9	A. I do.	
10	A. Yes. And I've also have and continue to do	10	Q. You state further into this recommendation	
1:	some straight stick laparoscopic, which means	11	section, "The group also recommends that patients be	
1:	Q. Without a robot?	12	made aware of the relative lack of long-term data on	
1:	A without robotic. Yes.	13	the durability of and adverse events associated with	
1	Q. You use the Davinci when you do robotic	14	vaginal graft use."	
1:	5 surgery?	15	You stand behind that statement?	
1		16	A. Can I give you a non-yes or no answer.	
1		17	Q. Well, first of all, what I'd like to know is	
18		18	when you wrote it and published it in November of	
19		19	2008, did you believe it to be true?	
20		20	MR. SNELL: Well, object to the form.	
2:		21	You're changing questions now?	
22		22	MR. SLATER: We're going back and	
23	-	23	, , ,	
24	• • • • • • • • • • • • • • • • • • • •	24		
2:	5 disagree with it?	25	MR. SNELL: There's multiple questions	
	Page 327			Page 329
-	Page 327 A. I would not.	1	on the table. You can answer the question how you	Page 329
	-	1 2		Page 329
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			on and Order of Confidentiality	
	Page 330			e 332
1	that risk, that lack of long-term data that we mention	1	Q. And you recommended at that time that	
2	about grafted repairs, I also believe to be 100% true	2	patients be made aware of that lack of long-term data,	
3	regarding native tissue repairs as well. When you're	3	correct?	
4	going through the editorial process in a peer-reviewed	4	A. I state that the group recommends that.	
5	journal, you get comments regarding things.	5	Q. The group on behalf of which you authored	
6	Q. Well, let's look a little bit above where we	6	this article, correct?	
7	just were reading.	7	A. Yes.	
8	A. Yes.	8	Q. If that was true in November of 2008, that	
9	Q. In fact, you stated, "Vaginal repairs with	9	would have been true when the Prolift® was launched in	
10	native tissue have been performed for decades, and	10	March of 2005, correct?	
11	although there are questions about the durability of	11	A. Correct.	
12	these repairs, the risks are well-known. In	12	Q. In fact, that continued to be true going	
13	particular, potential long-term sequelae are easier to	13	forward several years, correct, even up till the	
14	predict given the long track record of these	14	present, right?	
15	procedures."	15	A. We don't have ten-year data on vaginal graft	
16	Do you see that?	16	use placed vaginally.	
17	A. Yes, I do, and that's why I wanted to	17	Q. You certainly would agree that as of the	
18	qualify my answer, in that they are well known	18	time the Prolift® was launched, the important thing	
19	clinically because we've been doing them for years.	19	for patients to be made aware of was that there's a	
20	There are not studies that confirm that, and this is a	20	lack of long-term data on the durability of these	
21	paper looking at studies.	21	repairs with the Prolift®, and there's a lack of	
22	Q. But would you agree with me that as of the	22	long-term data regarding the adverse events associated	
23	time the Prolift® was launched, there was a relative	23	with the Prolift®, correct?	
24	lack of long-term data on the durability of and	24	A. Not really.	
25	adverse events associated with vaginal graft use?	25	MR. SNELL: Object to form. Go ahead.	
	Page 331		Page	e 333
1	A. I feel that way about vaginal graft use and	1	THE WITNESS: Not really.	
2	about native tissue repairs.			
1 -		2	BY MR. SLATER:	
3	MR. SLATER: Move to strike.	3	BY MR. SLATER: Q. That's fine. Let me ask you this: It	
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3		3	Q. That's fine. Let me ask you this: It	
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	Page 3			Page 336
	about in glowing terms in that brochure, that just		,	
2	understand whatever information we have on this is		C 1	
3	based on a similar but not identical procedure in all		s how you define indirectly.	
	respects, and we don't have long-term data on this,	4	•	
	just so the patient would understand where things	5	1	
6	stood. That should have been communicated in some	6	,	
7	way, correct?			
8	MR. SNELL: Objection, form.	3		
9	THE WITNESS: I think it was.	2		
10	BY MR. SLATER:	10	·	
11	Q. Well, you think it should have been	11	1 1	
12	communicated, correct?	12		
13	A. Yes. I think it should have been and I	13		
14	think it was.	14		
15	Q. And you think it was communicated in the	15		
16	patient brochure?	16		
17	A. Yes.	17	· ·	
18	Q. If it wasn't communicated in the patient	18	, , ,	
19	brochure, then you would have a criticism of the	19		
20	patient brochure, correct?	20		
21	A. Not necessarily.	21		
22	Q. You can't have it both ways, with all due	22		
23	respect.	23		
24	MR. SNELL: He can have an opinion, and		idea.	
25	it doesn't matter whether you like it or not.	25	Q. You certainly wouldn't have any information	
	D 2	235		Page 337
	Page 3	,55		rage 337
1	MR. SLATER: Boy, you're not as		to know what specific things physicians told patients	rage 337
1 2				rage 337
	MR. SLATER: Boy, you're not as	1		rage 331
2	MR. SLATER: Boy, you're not as friendly as you were a couple minutes ago. I'm going	1	in connection with the patient brochure if they did discuss it with a patient, right? It's not something	rage 337
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	Page 3:	8		Page 340
			A. I don't know whether they expected it. I	1 age 540
1	Q. Meaning I'm correct? A. You are correct.			
2	Q. Would you agree that it would be wrongful if	3		
3	any of the statements made in the patient brochure			
4	were inconsistent with what Ethicon's own	4		
5	understanding was with regard to a specific subject	5	A. Yes.	
6	addressed?	6		
7				
8	MR. SNELL: Objection, form.	8	THE VIDEOGRAPHER: Going off the	
9	MR. SLATER: What's your objection? You have objected to like 90% of my questions, so I'm	9	record, the time is 5:38 p.m. (Brief recess.)	
10	• •	10	· · · · · · · · · · · · · · · · · · ·	
11	going to call you out on this one.	11		
12	What's the objection to that one?	12		
13	MR. SNELL: It would be wrongful.	13	1 ,	
14	MR. SLATER: You don't know what	14	ī	
15	wrongful means?	15		
16	MR. SNELL: Inconsistent?	16	Q. Let's look at your clinical practice	
17	MR. SLATER: You don't know what inconsistent means?	17		
18		18	·	
19	MR. SNELL: No, I mean, I don't	19	After you state that the group recommends that patients be made aware of the relative lack of	
20	understand what you mean, is it wrongful if it's	20	•	
21	inconsistent?	21	long-term data on the durability of and adverse events	
22	MR. SLATER: With what Ethi	22	associated with vaginal graft use, there has been a	
23	MR. SNELL: In what manner? I mean,	23	· ·	
24		24	Do you see that? A. I do.	
25	of it? Is it wrongful? I don't know, maybe I	25	A. Tuo.	
_	D 0	0		Page 341
	Page 3.	19		rage 341
1	Page 3. don't understand.	1	Q. And in the article you list "Potential risks	rage 341
1 2				Fage 341
	don't understand.	1	include chronic pain, dyspareunia, fistula, infection	rage 341
2	don't understand. MR. SLATER: Do you understand the	1 2	include chronic pain, dyspareunia, fistula, infection	rage 341
2 3 4	don't understand. MR. SLATER: Do you understand the purpose of this litigation is partially to prove	1 2 3	include chronic pain, dyspareunia, fistula, infection and delayed graft erosion/exposure," correct?	rage 541
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		Page 342		0.5	Page 344
1	means that that would have to be something that was in		1	Q. Do you know what standards Ethicon was	
2	the Prolift® IFU.		2	required to follow in deciding whether or not risks	
3	Q. Are you saying you just don't know one way		3	needed to be listed in the IFU?	
4	or the other. It's just not something you're opining		4	A. I do not know those standards.	
5	on?		5	Q. Do you know what internally within Ethicon	
6	A. It's something that I'm saying that these		6	what Ethicon's understanding as to, from a standard	
7	are quoted here as potential risks and, therefore, I		7	level or from a general level, what risks would need	
8	don't know that it has to be in a Prolift® IFU.		8	to be included in an IFU for the Prolift®?	
9	Q. Well, let me ask you this: With regard to		9	MR. SNELL: Objection, form.	
10	the Prolift® IFU, do you have an opinion one way or		10	BY MR. SLATER:	
11	the other as to whether or not this list of potential		11	Q. Meaning how they would be able to make that	
12	risks, chronic pain, dyspareunia, fistula, infection		12	decision as to a particular risk to say, yes, this has	
13	and delayed graft erosion and exposure, are those		13	to be included, no, this doesn't; do you have any	
14	risks that should be in the Prolift® IFU?		14	idea?	
15	A. An IFU, as I understand it, is an		15	MR. SNELL: Objection, form. Go ahead.	
16	instructions for use. The goal, I would think, if I		16	THE WITNESS: There is a difference	
17	had a definition for instructions for use is to help		17	between whether I have any idea or whether I know. I	
18	instruct physicians, surgeons on how to do the		18	was never an employee of Ethicon. I don't know what	
19	Prolift® procedure. I think part of an IFU is to list		19	has to be in an instructions for use. I think part of	
20	potential complications. I think that's one of the		20	what should be in an instructions for use, because	
21	headings. I think that, again, you can't exhaustively		21	I've seen it in other instructions for use, is	
22	write every potential risk on there. They should list		22	potential risks and complications.	
23	things, I think, that are very specific to Prolift®		23	BY MR. SLATER:	
24	that one might not otherwise assume would be a risk of		24	Q. You would agree that the IFU for the	
25	pelvic reconstructive surgery.		25	Prolift® was intended to list the potential risks and	
		Page 343			D 245
1					Page 345
1	O Well with regard to these risks that you	rage 343	1	complications with the use of the Prolift® correct?	Page 345
1 2	Q. Well, with regard to these risks that you listed in this article in November of 2008, it would	rage 343	1	complications with the use of the Prolift®, correct? A. I don't think it was supposed to list every	Page 345
2	listed in this article in November of 2008, it would	rage 343	2	A. I don't think it was supposed to list every	Page 345
2 3	listed in this article in November of 2008, it would have been reasonable for Ethicon to list those risks	rage 343	2 3	A. I don't think it was supposed to list every one. I think it was supposed to list some and things	Page 345
2 3 4	listed in this article in November of 2008, it would have been reasonable for Ethicon to list those risks in the IFU, correct?	rage 343	2 3 4	A. I don't think it was supposed to list every one. I think it was supposed to list some and things that again were somewhat specific to this new	Page 345
2 3 4 5	listed in this article in November of 2008, it would have been reasonable for Ethicon to list those risks in the IFU, correct? MR. SNELL: Objection, form.	rage 343	2 3 4 5	A. I don't think it was supposed to list every one. I think it was supposed to list some and things that again were somewhat specific to this new procedure that they have just put out.	Page 345
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	Confidential - Subject to Si		LI		
		Page 346			Page 348
	and experience, but that may not be the level of		1	Was it Ethicon's intention to list the	
2	knowledge and experience of every person reading the		2	potential risks of using the Prolift® in the adverse	
3	IFU; you'd accept that, right?		3	event and warning section of the Prolift® IFU? Do you	
4	MR. SNELL: Object to form. Go ahead.		4	know if that was the intention?	
5	THE WITNESS: Well, if they're doing a		5	A. I don't know what their intent was. I	
6	Prolift®, then they should be, according to the IFU,		6	wasn't employed by them.	
7	familiar with pelvic reconstructive surgery and		7	Q. Did you look at any internal Ethicon	
8	familiar with placing permanent grafts. So that's		8	documents or deposition testimony that you can tell me	
9	kind of like me.		9	about now that addressed that question?	
10	BY MR. SLATER:		10	A. I don't recall exactly. I know I read some	
11	Q. Well, somebody who is familiar with pelvic		11	of Piet Hinoul's deposition. It may have been	
12	reconstructive surgery could be somebody who learned		12	addressed there, but I can't recall specifics.	
13	about it during the residency, never did a fellowship,		13	Q. In offering well, rephrase.	
14	did a handful of colporrhaphys and did four SUI		14	As you sit here now, can you tell me any	
15	slings. That would make them familiar with pelvic		15	standard or any test that would apply to the question	
16	reconstructive surgery and the use of mesh, correct?		16	of whether or not a risk needed to be included in the	
17	A. If that's how you want to categorize		17	IFU? I mean, is there any specific standard or test	
18	familiar, you can, but that's not how I would		18	you can point to and say this is the test that	
19	categorize it.		19	applies, and this is how I can tell you whether or not	
20	Q. What I'm saying is if you just read the		20	a risk needed to be listed or not?	
21	words on the page, what I just described to you would		21	A. My opinion to that would be that it would	
22	be somebody who has some level of familiarity, right?		22	the IFU should list things that a reasonable surgeon	
23	MR. SNELL: Objection, form.		23	who is familiar with pelvic reconstructive surgery	
24	THE WITNESS: I'd like to read the		24	wouldn't automatically think would otherwise be a risk	
25	words on the page, rather than deal in hypotheticals.		25	of Prolift®.	
		Page 347			Page 349
1	BY MR. SLATER:	Page 347	1	Q. Taking that definition	Page 349
1 2	BY MR. SLATER: Q. Well, it says familiar with, right?	Page 347	1 2	A. Yes.	Page 349
	BY MR. SLATER: Q. Well, it says familiar with, right? A. I don't know exactly what it says.	Page 347		A. Yes.Q what are the risks of the Prolift® that	Page 349
2 3 4	BY MR. SLATER: Q. Well, it says familiar with, right? A. I don't know exactly what it says. Q. The IFU says users should be familiar with	Page 347	2	A. Yes. Q what are the risks of the Prolift® that should be listed in the IFU? Give me that list.	Page 349
2 3 4 5	BY MR. SLATER: Q. Well, it says familiar with, right? A. I don't know exactly what it says. Q. The IFU says users should be familiar with surgical procedures and techniques involving pelvic	Page 347	2	 A. Yes. Q what are the risks of the Prolift® that should be listed in the IFU? Give me that list. A. Mesh erosion, potentially mesh contraction, 	Page 349
2 3 4 5	BY MR. SLATER: Q. Well, it says familiar with, right? A. I don't know exactly what it says. Q. The IFU says users should be familiar with	Page 347	2 3 4	A. Yes. Q what are the risks of the Prolift® that should be listed in the IFU? Give me that list.	Page 349
2 3 4 5	BY MR. SLATER: Q. Well, it says familiar with, right? A. I don't know exactly what it says. Q. The IFU says users should be familiar with surgical procedures and techniques involving pelvic	Page 347	2 3 4 5	 A. Yes. Q what are the risks of the Prolift® that should be listed in the IFU? Give me that list. A. Mesh erosion, potentially mesh contraction, 	Page 349
2 3 4 5 6	BY MR. SLATER: Q. Well, it says familiar with, right? A. I don't know exactly what it says. Q. The IFU says users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing	Page 347	2 3 4 5 6	 A. Yes. Q what are the risks of the Prolift® that should be listed in the IFU? Give me that list. A. Mesh erosion, potentially mesh contraction, puncture of organs, meaning damage to surrounding 	Page 349
2 3 4 5 6 7	BY MR. SLATER: Q. Well, it says familiar with, right? A. I don't know exactly what it says. Q. The IFU says users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the Gynecare Prolift® pelvic floor repair systems?	Page 347	2 3 4 5 6 7	 A. Yes. Q what are the risks of the Prolift® that should be listed in the IFU? Give me that list. A. Mesh erosion, potentially mesh contraction, puncture of organs, meaning damage to surrounding structures with the introducing devices. 	Page 349
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	Confidencial - Subject to Scipula	LLI	on and order or confractional	
	Page 350			Page 352
1	standpoint.	1	Q. If there was a patient population that the	
2	Q. Is there well, let me ask you this: The	2	people in Ethicon thought needed to be rephrase.	
3	standard you just gave me of what you think should be	3	If there was a patient population that	
4	in an IFU, is that just your own personal standard?	4	Ethicon thought physicians should show caution with	
5	A. That was my opinion of what makes sense to	5	before placing a Prolift®, did that need to be	
6	be in an IFU.	6	communicated in the IFU?	
7	Q. That's your own personal opinion, not based	7	A. If Ethicon knew of a particular patient	
8	on any other information you've read or seen, correct?	8	condition that they thought was particularly at risk	
9	A. Correct.	9	of a Prolift®, that that should be communicated in the	
10	Q. It's just your own personal viewpoint, your	10	IFU; is that the question?	
11	own personal standard, correct?	11	Q. Let's start with that.	
12	A. Yes.	12	A. Yes, I think that's reasonable.	
13	Q. With regard to what would need to be	13	Q. And Ethicon didn't have to know it 100%,	
14	included in the patient brochure with regard to risks	14	they just had to have enough information for it to be	
15	and benefits, to the extent you've drawn any opinions	15	reasonable to communicate that, correct?	
16	in your report on that, again, is that based on your	16	MR. SNELL: Objection, form.	
17	own personal standard, your own personal opinion?	17	BY MR. SLATER:	
18	A. I do not I think the answer is yes	18	Q. Or do you not know?	
19	because I don't know any sort of legal guidelines by	19	A. It all depends on what reasonable means.	
20	which patient brochures are supposed to be produced.	20	Q. Okay. If Ethicon knew of a type of patient	
21	Q. And do you have any information you can	21	that Ethicon thought physicians should show caution	
22	share with me now that you gleaned from any Ethicon	22	for because of their characteristics, like young,	
23	documents or testimony where you saw what Ethicon	23	sexually active women, before recommending the	
24	thought the standards were to determine whether or not	24	Prolift® to them, did Ethicon need to communicate that	
25	a risk or a benefit would need to be described and how	25	in the IFU to surgeons?	
25	a risk of a benefit would need to be described and now	25	in the free to surgeons:	
		1		
	Page 351			Page 353
1	Page 351 it should be described in a patient brochure?	1	A. No.	Page 353
1 2		1 2	A. No. Q. They could just assume that surgeons would	Page 353
	it should be described in a patient brochure?			Page 353
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	Page			age 356
1	A. Yes.	1		
2	Q. Do you know, as you sit here now, based on	2		
3	whatever you've reviewed, what the potential risks of	3		
4	the Prolift® were from the perspective of what medical	4	,	
5	affairs in Ethicon knew?	5	MR. SNELL: Objection, form. Go ahead.	
6	A. I do not know what medical what that	6	THE WITNESS: What do you mean by	
7	group knew.	7	"affirmative statements"?	
8	Q. Would you assume that Ethicon medical	8	BY MR. SLATER:	
9	affairs would have more information about the overall	٥	Q. When Ethicon made statements in the IFU, did	
10	potential risks of the Prolift® than you would have?	10	those statements need to be truthful?	
11	MR. SNELL: Objection, form.	11	A. I think anything that Ethicon produces	
12	THE WITNESS: I don't know how that	12	should be truthful.	
13	MR. SNELL: He's not here to assume.	13	Q. When Ethicon made statements making claims	
14	MR. SLATER: Well, he is, actually.	14	about the Prolift®, did they need to have support for	
15	You can answer.	15	those claims, in your opinion?	
16	THE WITNESS: I don't know if they'd	16	A. I guess it would depend on what the claims	
17	know more. I think they would know probably most that	17	were.	
18	I would.	18	Q. Well, if Ethicon made a claim about the	
19	BY MR. SLATER:	19	attributes of the mesh material in terms of how it	
20	Q. As you sit here now, you don't know whether	20	would behave inside the body and what its	
21	Ethicon medical affairs well, rephrase.	21	characteristics were, did those claims need to be	
22	As you sit here now, you don't know what	22	backed up by data that Ethicon could rely on, so if	
23	risks Ethicon medical affairs has testified to knowing	23	someone said, hey, what's your basis for saying this,	
24	about at different points in time, correct?	24	Ethicon can say, well, here's my basis, here's the	
25	A. I can't recall any testimony that I saw	25	data?	
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	Page			age 357
	regarding that.	1	Do you think that's something that was	age 357
2	regarding that. Q. You certainly didn't talk about that subject	1 2	Do you think that's something that was required?	age 357
2 3	regarding that. Q. You certainly didn't talk about that subject in your reports, correct?	1 2	Do you think that's something that was required? MR. SNELL: Objection, form.	age 357
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	Doo	250			Daga 260
1		ge 358	1	If that's what occurred, the statement never	Page 360
1 2	MR. SLATER: Listen, you're wrong. Let's continue.		1 2 s	should have been in the IFU to begin with, right?	
3	BY MR. SLATER:		3	MR. SNELL: Objection, form.	
4	Q. Did you see what Ethicon's new question.		4	THE WITNESS: It's a pretty general	
5	Did you see what Ethicon told the FDA with		_	statement that it can react to different forces. If	
6	regard to the statement, the bidirectional elastic			t has stretching in both directions and that implies	
7	property allows adaptation to various stresses			that if you push from one way, it can stretch one way.	
	encountered in the body?			if you push from another, it can stretch from another.	
8	A. I don't recall.			mean, it's hardly I don't think it's some huge	
9	Q. If Ethicon did not have data that it could			falsehood that they were trying to perpetrate on	
10					
11	produce to the FDA to document that this elastic			loctors and patients. BY MR. SLATER:	
12	property would, quote, allow adaptation to various				
13	stresses encountered in the body, closed quote, that statement should not have been made in the IFU,		13	Q. Do you have any idea where that statement came from?	
14				A. I do not.	
15	MP SNELL Objection form		15		
16	MR. SNELL: Objection, form.		16 17 (Q. Would it surprise you to learn that all they did was copy out of the IFU that statement from	
17	THE WITNESS: I can hold a piece of Gynemesh® mesh in my hand and stretch it both ways.			another product and that it had actually been used in	
18	•			yet another product before that, and they just	
19	If that's not evidence enough for the FDA, then I			pasically copied it and assumed there must be support	
20	guess they have a difference of opinion of what			7 1	
21	constitutes good evidence.			for it if it was used somewhere else, and we'll just	
22	BY MR. SLATER:			copy it; is this the first time you're hearing that?	
23	Q. Well, let's listen to the sentence.		23	MR. SNELL: Objection, form.	
24	A. Okay.		24	THE WITNESS: Wait. First you asked	
25	Q. The sentence says, the bidirectional elastic		25 v	would it surprise me. Now you're asking me is it the	
	Pag	ge 359			Page 361
1	Pag property, okay, that's the first half.	ge 359	1 f	first time I've heard it.	Page 361
1 2		ge 359		first time I've heard it. BY MR. SLATER:	Page 361
	property, okay, that's the first half.	ge 359			Page 361
2	property, okay, that's the first half. A. Yes.	ge 359	2 I	BY MR. SLATER:	Page 361
2 3 4	property, okay, that's the first half. A. Yes. Q. That means it can stretch in two directions?	ge 359	2 I	BY MR. SLATER: Q. Well, would it surprise you, since you,	Page 361
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	Page 262	101		Dogo 264
	Page 362		DV MD GLATTED	Page 364
1	A. What I hope is when they produce an IFU that		BY MR. SLATER:	
	it's not misleading me.	2	Q. Have you ever studied the question of	
3	Q. When you read the Prolift® IFU in your own	3		
4	practice, you assumed that whatever was being stated	4	medical devices?	
5	in that IFU was information that Ethicon could back up	5	A. From a scientific standpoint?	
6	with data, right?	6	Q. On any level have you ever studied the	
7	A. I don't recall ever reading the Prolift®	7	•	
8	IFU.	8	A. No.	
9	Q. In your practice, you don't think you ever	9	Q. You've never there's not even a	
10	read it?	10	conversation you can point to now that you can recall	
11	A. Not that I recall.	11		
12	Q. Do you have any opinion as to whether or not	12	A. I just said that.	
13	surgeons in general read the Prolift® IFU before they	13	Q. When Ethicon promulgate well, rephrase.	
14	use the Prolift®?	14	When Ethicon puts the IFU in the box with	
15	A. I think that some surgeons may review it the	15	Prolift®, is it appropriate for Ethicon to assume,	
16	night before they do their very first one. That's	16	well, you know what, some doctors aren't even going to	
17	about the best I can testify. I really it's hard	17	bother reading this, so we don't have to be careful	
18	for me to speak for all the surgeons out there in the	18	about being able to back up everything we say; is that	
19	world.	19	okay?	
20	Q. Are you basically just guessing as you say	20	MR. SNELL: Objection, form.	
21	that, I mean, or do you have any basis to know?	21	THE WITNESS: Is it okay for Ethicon to	
22	A. I'm basing it on what it's like to do a	22	not care about what's in IFU? No, it's not. I think	
23	procedure for the first time.	23	that was the basic gist of that question.	
24	Q. For you to do a procedure for the first	24	BY MR. SLATER:	
25	time?	25	Q. The mesh in the Prolift® causes a chronic	
	Page 363			Page 365
1		1	inflammatory reaction, correct?	1 age 303
1	A. And in talking to my colleagues.		inflammatory reaction, correct?	1 age 303
2	A. And in talking to my colleagues.Q. Have you ever discussed with anybody whether	2	A. I guess it depends on how you define	1 age 505
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	Confidencial - Subject to Scipul	_		D 260
	Page 366			Page 368
1	Do you see that?	1	A. I'll have to read through it. (Witness	
2	A. I see Adverse Reactions.	2	•	
3	Q. "Potential adverse reactions are those	3	contraindications, which I think, you know, implant	
4	typically associated with surgically implantable	4	contraction could refer to those, since it states that	
5	materials." Do you see that?	5	the product will not stretch significantly as the	
6	A. Yes.	6	patient grows, for instance, someone who is going to	
7	Q. When this IFU refers to surgically	7	be pregnant or is a child.	
8	implantable materials, do you know what is being	8	Q. That's it?	
9	referred to?	9	A. That's it.	
10	A. I think it's referring to mesh.	10	Q. The sentence that you just referred to in	
11	Q. And why do you assume that?	11	the contraindications makes no that sentence makes	
12	A. Because this is an IFU about a mesh product.	12	no reference to contraction of the implant, correct?	
13	Q. Mesh is not the only surgically implantable	13	A. Right, it does not.	
14	material, correct?	14	Q. In the Adverse Reactions section where it	
15	A. It is not.	15	states "scarring that results in implant contraction,"	
16	Q. There are many others that are different	16	there is absolutely no description of the potential	
17	from mesh, correct?	17	consequences of that implant contraction, correct?	
18	A. Correct.	18	A. Correct.	
19	Q. Do they all have the same potential adverse	19	Q. One of the risks of the Prolift® is vaginal	
20	reactions, mesh versus other surgically implantable	20	anatomic distortion, correct?	
21	materials?	21	A. Are you saying that that's stated here?	
22	A. I would say infection potentiation, yes.	22	Q. I'm asking you, first of all, one of the	
23	Inflammation, I would say yes. Adhesion formation, I	23	risks of the Prolift® is that when a Prolift® is	
24		24	placed in a woman's body, she can develop vaginal	
	Erosion, I would say no. Extrusion, I would say no.	25	anatomic distortion, correct?	
			,	
	D 245			
	Page 367			Page 369
1		1	A. I mean, distortion compared to how she was	Page 369
		1 2	A. I mean, distortion compared to how she was beforehand, absolutely. I mean, it was out, now it's	Page 369
	Scarring that results in implant contraction, I would		•	Page 369
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			on and order or confractionally
	Page 370)	Page 372
1	•	1	Q. Physicians who would be potential users of
2		2	the Prolift®.
3		3	A. I think there was a fair amount of data on
4	particular risks would need to be listed, correct?	4	vaginal erosions of mesh when it was placed vaginally.
5	A. From a law standpoint?	5	Q. Well, my question is was there well,
6	Q. From the standpoint of what a medical device	6	rephrase.
7	manufacturer should do when promulgating an IFU.	7	Do you have an opinion as to what the
8	A. Again, I'm not well versed in what are the	8	understanding was among surgeons who might be Prolift®
9	guidelines for developing IFU.	9	users as to whether or not the risk of exposure of the
10	Q. The Warnings and Precautions, the second to	10	mesh was something that would generally manifest in
11	last bullet point says, "Transient leg pain may occur	11	the short term if it was going to happen?
12	and can usually be managed with mild analgesics."	12	A. It's hard for me to recall what I thought
13	Do you see that?	13	other physicians thought in 2005. I can certainly say
14	A. I do.	14	my opinion on that now, but I would have trouble
15	Q. Do you have any idea why that's listed	15	testifying as to what my thoughts were at that time.
16	there?	16	Q. Would you agree with me that the risks with
17	A. I think because it's a sort of unique risk	17	regard to the Prolift® are better understood now than
18	of Prolift® that in standard reconstructive surgery	18	they were in March of 2005 when the Prolift® first
19	wasn't there. So, for instance, you're doing passes	19	went on the market?
20	through the obturator canal, through the abductor	20	A. Yes.
21	muscles of the thigh. When you do an anterior	21	Q. Tell me how.
22	colporrhaphy, you're not going through the obturator	22	A. As we've stated multiple times in this
23	canal. So it's sort of a unique thing that Prolift®	23	deposition, the Prolift®, as we're defining it, had
24	brings to the table.	24	not been done prior to 2005. So it would stand to
25	Q. In those transobturator passes, are there	25	reason that we've learned something since then.
	Page 37		Page 373
1		1	Page 373 Q. Tell me what risks from your perspec
1 2	other risks besides transient leg pain?		Q. Tell me what risks from your perspec
	other risks besides transient leg pain?	1	Q. Tell me what risks from your perspec
2	other risks besides transient leg pain? A. Yes.	1 2	Q. Tell me what risks from your perspec rephrase.
2	other risks besides transient leg pain? A. Yes. Q. What?	1 2 3	Q. Tell me what risks from your perspec rephrase. Tell me what risks with regard to the
2 3 4	other risks besides transient leg pain? A. Yes. Q. What? A. Injury to surrounding organs.	1 2 3 4	Q. Tell me what risks from your perspec rephrase. Tell me what risks with regard to the Prolift® are better understood now than they were when
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	Page 37	4	Page	376
	March of 2005? You've told me you understood there	1	A. Only to the extent that I just talked about,	
2	was a risk of erosion, but if I'm understanding, the	2	1	
3	nuances of that risk, the details of that risk are	3	did not exist prior to its launch.	
4	better understood now?	4	Q. Well, whatever understanding you had about	
5	A. Correct.	5	the potential risks with the Prolift® when it was	
6	MR. SNELL: Objection to form.	6	launched would have been, to some extent, guided by	
7	BY MR. SLATER:	7		
8	Q. Tell me how.	8	A. Yes, absolutely.	
9	A. Well, I generally thought at that point	9	Q. Okay. And as comparing what you understood	
10	that, for the most part, when erosions were going to	10	about, for example, the risk of erosion as of March	
11	occur, it was going to occur within the first year,	11	of 2005 and as compared to now, have you learned	
12	that you could have late erosions, but they were	12	anything further of any significance with regard to	
13	usually going to be pretty rare, but I couldn't say	13	that risk with regard to the Prolift®?	
14	that with any certainty about the exact Prolift®	14	A. I wouldn't say of any significance, no.	
15	system then because it had just come out.	15	Q. How about with regard to any risk, anything	
16	Now, I now have data that essentially tell	16	of significance you've learned since the launch of the	
17	me the same things, but I didn't know it back then for	17	Prolift® in March of 2005?	
18	sure.	18	A. In terms of risk of recurrence, I think I've	
19	Q. Anything else that you have learned about	19		
20	erosion?	20	Q. What?	
21	A. Of Prolift®?	21	A. You know, there's a question as to whether	
22	Q. Yes.	22	or not to do a hysterectomy at the time of Prolift®	
23	A. Learned ways in which to manage it.	23	was something that was being discussed in academic	
24	Q. What do you mean by that?	24	circles around that time, and some of the TVM data	
25	A. Again, I hate to harp on this, but if you're	25	suggested that if you do a hysterectomy at the time of	
	Page 37	5	Page	377
1	Page 37 going to make a big differential between TVM and	5 1		377
			the TVM, that was going to increase your risk of	377
	going to make a big differential between TVM and	1	the TVM, that was going to increase your risk of	377
2 3	going to make a big differential between TVM and Prolift®, I'm just going to have to say that we	1 2	the TVM, that was going to increase your risk of erosion. So, therefore, we when Prolift® came out,	377
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		Page 378		Page 380
1	Prolift+M® group.		1	Prolift+M® came on the market and Gynecare applied for
2	Q. Since March of 2005 has your knowledge with		2	a 510(k) approval and it became the FDA became
3	regard to the inflammatory process, the foreign body		3	aware that Prolift® itself had not gotten 510(k)
4	reaction, the formation of fibrosis evolved at all?		4	approval, and they went back and granted 510(k)
5	MR. SNELL: Can you repeat that		5	approval to Prolift® and, therefore, some changes were
6	question.		6	made. I think it was in relation to that.
7	(The court reporter read back the		7	Q. Do you know why the changes were made to the
8	record as requested.)		8	Prolift® IFU; meaning, do you know why Ethicon decided
9	MR. SNELL: Objection, form.		9	to make those changes? Was it on their own, or did
10	THE WITNESS: Not substantially.		10	the FDA have input; do you have any idea?
11	BY MR. SLATER:		11	A. I don't know for sure. I think that it
12	Q. At all?		12	something to do with the FDA, but I could be wrong
13	A. I can't point to specific instances I could		13	about that.
14	tell you about.		14	Q. Did you ever sit down and compare the 2009
15	Q. If you could, take a look at your SGS		15	IFU to the IFU that was in effect before that to see
16	article from November of 2008, the clinical practice		16	what was different?
17	guidelines.		17	A. I think in the preparation of coming to this
18	A. Yes.		18	deposition, I did look at both of them.
19	Q. Page 1129. You state at the top of the		19	Q. Did you see any rephrase.
20	right-hand column in the third line, "In order for		20	Any of the things that were changed and
21	women to give true informed consent."		21	added or modified, if those changes made the
22	A. I'm sorry, top of the right-hand column.		22	information more accurate, you would agree that that
23			23	is what it should have said from day one, right?
24	Q. Yes. Third line?		24	A. Not really.
25	A. Yes, I see it.		25	MR. SNELL: Objection, form. Go ahead.
25	A. Tes, 1 see it.		25	MR. SIVELE. Objection, form. Go allead.
			_	
		Page 379		Page 381
1	Q. "In order for women to give true informed	Page 379	1	Page 381 THE WITNESS: Not really. I mean, I
1 2	Q. "In order for women to give true informed consent, we as surgeons must convey the unique risks	Page 379	1 2	•
	· ·	Page 379		THE WITNESS: Not really. I mean, I
2	consent, we as surgeons must convey the unique risks	Page 379	2	THE WITNESS: Not really. I mean, I don't put that much importance on IFU. You're asking
2	consent, we as surgeons must convey the unique risks related to grafts and the lack of long-term data	Page 379	2	THE WITNESS: Not really. I mean, I don't put that much importance on IFU. You're asking me my expert opinion. That's my opinion.
2 3 4	consent, we as surgeons must convey the unique risks related to grafts and the lack of long-term data comparing native tissue repair to vaginal graft use to	Page 379	2 3 4	THE WITNESS: Not really. I mean, I don't put that much importance on IFU. You're asking me my expert opinion. That's my opinion. BY MR. SLATER:
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	Confidencial - Subject to Scipula			
	Page 382			Page 384
1	along those lines.	1	to be honest with you. I'm not haven't read this	
2	Q. Is that considered to be a high powered	2	in a while.	
3	journal?	3	Q. Well, let me ask you a clean question.	
4	A. I would say no.	4	A. Okay.	
5	Q. Go to the second page please, Page 326, left	5	Q. Regardless of what the rate is for new-onset	
6	column under the heading in the middle of the page.	6	dyspareunia with women getting Prolifts®, let's talk	
7	Go down good five lines, just after reference 11.	7	about Prolifts®, whatever that rate is would be	
8	You state, "Obviously, the female pelvis is	8	irrelevant to a woman who is sexually active and	
9	substantially different in many aspects when compared	9	actually develops it because of the impact on her	
10	with the abdominal wall."	10	individual quality of life; fair statement?	
11	That's a true statement, correct?	11	A. Yes.	
12	A. Yes.	12	Q. And the reason being that even if there's	
13	Q. And if you go over to the just directly	13	benefit to some number of women, if you get a very	
14	across the page, the other column, you state, "As	14	serious complication like dyspareunia and it doesn't	
15	mentioned, the vagina does have unique differences	15	go away, that can be very devastating on the women	
16	when compared with the abdominal wall."	16	that do get it, correct?	
17	Do you see that?	17	A. Correct. Plane travel is very safe, but for	
18	A. Yes.	18	someone who dies in a plane crash, it's very	
19	Q. True statement, correct?	19	significant for them.	
20	A. Correct.	20	Q. And if someone develops a plane that they	
21	Q. And when you a little further down, you	21	think is going to get better gas mileage, but then it	
22	state that "unique considerations to the vagina in the	22	turns out that even if it is getting somewhat better	
23	use of mesh-augmented repair," and then you list some	23	gas mileage, there's also more crashes occurring	
	of those in bullet points, correct?	24	because the part that you had to change on it to get	
25	A. Correct.	25	the gas mileage causes a new risk for it to crash, you	
23	A. Concet.	23	the gas fiffeage causes a new fisk for it to clash, you	
	Page 383			Page 385
1	Page 383 Q. One of them is that the surgical site cannot	1	probably want to take that plane off the market,	Page 385
1 2		1 2	probably want to take that plane off the market, right?	Page 385
	Q. One of them is that the surgical site cannot			Page 385
2	Q. One of them is that the surgical site cannot be sterilized, correct?	2	right?	Page 385
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		Page 386	Page 388	3
	1 Q. I'm not. What I'm actually asking you is		1 it was launched.	
	2 this: When Ethicon markets the Prolift® that's what		2 Q. Are you aware of anything else that Ethicon	
	3 they're offering for sale and asking for money back		3 had available to it by way of information about the	
	4 for, so Ethicon's obligations are limited to the		4 risks and benefits of the Prolift® once it was	
	5 Prolift®. Ethicon doesn't have to worry about		5 launched in an ongoing basis?	
	6 alternative procedures and whether or not people are		6 A. I know the MAUDE database exists. I don't	
	7 going to get those. Ethicon has to worry about are we		7 know if things get reported to Ethicon if something	
	8 being responsible in marketing this Prolift®, correct?		8 goes to there that's specifically Prolift®, I don't	
	9 MR. SNELL: Objection, form.		9 know that for sure, but maybe that's something. Other	
=	0 BY MR. SLATER:		10 than that, no, I don't.	
=	Q. Do you understand that?		11 Q. You don't have an understanding of the	
:	2 A. I'm understanding that what, again, you seem		12 mechanisms by which complaints can be made to Ethicon	
-	3 to be implying is that if there's a risk with a		13 and whether or to what extent those would be looked	
:	4 product that someone should not market it.		14 at?	
:	5 Q. No, that's not what I'm saying.		15 A. So do I know that if someone sent a	
:	6 A. Okay. Well, it sounded like that to me.		16 complaint to Ethicon about their product, whether or	
:	7 Q. What I'm saying is this: Do you have any		17 not they'd review it?	
-	8 understanding if you don't know or it's something		Q. Do you know what would happen with that	
:	9 you don't feel comfortable talking about, you can say		19 complaint; do you have any information?	
1	0 I'm not going to get into that area.		20 A. Not specifics. I assume it would go to	
1	Do you have an understanding about whether a		21 someone in the company and they would review it.	
1	2 medical device manufacturer like Ethicon needs to		22 Q. Beyond that, you don't know anything	
1	weigh, in some instances, the risk of very		23 specific?	
2	4 catastrophic complications to some minority of women		24 A. I do not know, no.	
1	that are going to get it against a potential benefit		25 (Document marked for identification	
\vdash		D 207	D 200	_
		Page 387	Page 389)
	1 to other women, and in some cases, needs to say, you	Page 387	1 as Murphy Deposition Exhibit No. 6.))
	1 to other women, and in some cases, needs to say, you2 know what, there's enough getting these very	Page 387	1 as Murphy Deposition Exhibit No. 6.) 2 BY MR. SLATER:)
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	Confidencial - Subject to Scipula			
	Page 390			Page 392
1	A. Okay.	1	Q. And that would just be in women with severe	
2	Q. On Page 1282 at the top right-hand corner,	2	cases of prolapse, correct?	
3	four lines down, there's a sentence that says, "We	3	A. No. The ulceration is only going to happen	
4	recently published data showing that pelvic organ	4	if you have prolapse beyond the introitus, but in	
5	prolapse was not a cause of pelvic or lower back	5	terms of the sensation of pressure and heaviness and	
6	pain."	6	discomfort, that can be in nonsevere prolapse as well.	
7	Do you see that?	7	Q. Generally, you would expect that only in	
8	A. I do.	8	someone who is Stage 3 or 4, correct?	
9	Q. True statement?	9	A. I would not say that.	
10	A. The article, let me look at it, I know it	10	Q. Not as a general proposition?	
11	was a Heit publication, is pelvic organ prolapse a	11	A. No.	
12	cause of pelvic or low back pain. My understanding of	12	MR. SLATER: Can we go off the record	
13	that study was that a lot of people who present with	13	for about five minutes. I'm going to organize my	
14	pelvic organ prolapse also have lower back pain, and	14	notes a little, try to move through this a little	
15	to the extent that we could statistically look at it	15	quicker.	
16	and see the correlation between prolapse and lower	16	THE VIDEOGRAPHER: Going off the	
17	back pain, we could not see a definite correlation.	17	record. The time is 7:01 p.m.	
18	Certainly, in my own practice, I have lots	18	(Brief recess.)	
19	of patients that complain of low back pain that they	19	THE VIDEOGRAPHER: We're back on the	
20	think is related to their prolapse. I certainly have	20	record. Here marks the beginning of Volume 1, Tape	
21	lots of patients in whom I fix their prolapse and	21	Number 7, the deposition of Dr. Miles Murphy. The	
22	their low back pain gets better, but in terms of a	22	time is 7:16 p.m.	
23	sort of quintessential symptom of pelvic organ	23	BY MR. SLATER:	
24	prolapse, that one study that is quoted here, Number	24	Q. I've handed you Exhibit 3008, which is a	
	5, showed that they're not highly correlated.	25	article titled Safety of Transvaginal Mesh procedure:	
23	5, showed that they to not highly contributed.	23	article titled barety of Transvaginar iviesh procedure.	
	Page 391			Page 393
1	Page 391 Q. The Reference Number 5	1	Retrospective study of 684 patients written by mostly	Page 393
1 2		1 2		Page 393
	Q. The Reference Number 5			Page 393
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	Confidential - Subject to Stipu		on and order or confractional	
	Page 39			Page 396
1	A. Yes.	1	Q. Do you know what the exact shape was of the	
2	Q. It involved surgeries performed on 684		implant as used by these TVM physicians in this study?	
3	patients between October 2002 and December 2004 at	3	A. I've seen other descriptions of TVM mesh	
	various hospitals in France, correct?		from TVM studies that looks slightly different than	
5	A. Correct.	5	this.	
6	Q. It says in the results section of the	6	Q. If you look at Page 452, I have a few	
7	abstract, the mean follow-up period was 3.6 months.	7	1 0	
8	You see that?	8	There's a section on Page 452 of this	
9	A. Yes.	9	article titled Late Postsurgical Complications.	
10	Q. In the results section of the abstract,	10	A. Yes.	
11	there's a list of what are referred to as late	11	Q. And it indicates that 157 late postsurgical	
12	postsurgical complications.	12	complications were noted, correct?	
13	Do you see that?	13	A. 157 late yes.	
14	A. No. How far down?	14	Q. And then it says, the most frequent was	
15	Q. About halfway through there's a reference to	15	vaginal exposition of prosthesis, which they put at	
16	early postsurgical complications.	16	11.3%, correct?	
17	A. Yes.	17	A. Correct.	
18	Q. Which are defined as the first month after	18	Q. That would be exposure, correct?	
19	surgery.	19	A. I think that's what they're referring to,	
20	Do you see that?	20	yes.	
21	A. Yes.	21	Q. And they say 46 of those women required	
22	Q. And then what they call late postsurgical	22	treatment, right?	
23	complications, and then they give some percentages of	23	A. Correct.	
24	those.	24	Q. So if you go up to the top of the next	
25	Do you see that?	25	column, the second full paragraph with regard to the	
	Page 39	5		Page 397
1	Page 39 A. I see that.	5 1	exposures, 42% were able to be treated medically and	Page 397
1 2		1	exposures, 42% were able to be treated medically and 57.8% needed surgery, correct?	Page 397
	A. I see that.	1	•	Page 397
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	market the Prolift®, correct?		retraction and exposure, correct?	
2	A. Certainly, yes.	2	MR. SNELL: Objection. You said	
3	Q. And if Ethicon had information about the	3	statistically?	
4	data reflected in this article, Ethicon needed to take	4	MR. SLATER: Yes.	
5	that information into account in writing the warnings	5	MR. SNELL: All right. Objection.	
6	and information in both the IFU and the patient	6	THE WITNESS: I've already stated my	
7	brochure, correct?	7	opinion about retraction. This situation that they're	
8	A. It had to take it into account, yes.	8	talking about, someone who has a retraction and they	
9	Q. And with regard to any of the data that had	9	needed surgery to go in to correct that, that's along	
10	been compiled by the French TVM group, whether it was	10	the lines of that complication that I talked about	
11	published or whether it was just available to Ethicon	11	with the patient of mine, where it felt like there was	
12	before launch, the same would hold true, correct?	12	too much tension on one of the arms and wanted to go	
13	A. I'm sorry. Say that again.	13	in and release it.	
14	Q. With regard to any data that the French TVM	14	I don't necessarily, again, believe	
15	group had that Ethicon was privy to, whether it was	15	that that truly represents a contraction, and I don't	
16	published or not, Ethicon had to similarly take that	16	know if that's a French to English difference in terms	
17	into account, correct?	17	of how they view that or not, but that's a phenomenon	
18	A. Yes.	18	that if you're just saying it's truly a contraction, I	
19	MR. SNELL: Objection to form.	19	don't really think exists, but that's what they're	
20	BY MR. SLATER:	20	calling it.	
21	Q. And they would have had to take that	21	BY MR. SLATER:	
	•		Q. I'm only presenting to you what's written in	
22	information and that data into account in deciding	22	- , , , , , , , , , , , , , , , , , , ,	
23	whether to market the Prolift®, correct?	23	this article by the French TVM doctors.	
24	A. They'd have to take it into account, yes.	24	A. Right, I understand, but there's they're	
25	Q. And they would have to take it into account	25	calling it a contraction. I don't know that it's my	
	Page 399			Page 401
	č			
1	in providing the warnings and information in the IFU	1	opinion that that's really what it is.	
1 2		1 2	opinion that that's really what it is. Q. In this article they point out that over	- 1.82
	in providing the warnings and information in the IFU		,	- 1.00
2	in providing the warnings and information in the IFU and the patient brochure, correct?	2	Q. In this article they point out that over	- 110
2	in providing the warnings and information in the IFU and the patient brochure, correct? MR. SNELL: Objection, form.	2	Q. In this article they point out that over 50%, 52.6% to be precise, of the retractions were	- 1.6
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	Page 402		Page 404	
	exposure; is that where you are?	1	lines up from the bottom of the page, there's a	
2	Q. Yeah, next paragraph.	2	sentence that starts, prosthetic retractions.	
3	A. Complications of prosthetic, okay.	3	Do you see that?	
4	Read the part that you want me interested	4	A. I do.	
5	in.	5	Q. It says, prosthetic retractions were not	
6	Q. On the right-hand column of Page 453, the	6	systematically looked for in any of the centers when	
7	authors state, retractions and relapse of prolapse	7	the study began so results may have been biased in our	
8	were also significantly linked.	8	study for our different observers.	
9	Do you see that?	9	That's basically saying that they were not	
10	A. Retractions and relapse of prolapse were	10	as a point of the study looking for retraction of the	
11	also significantly linked. Yes, I saw that.	11	mesh so they may have missed some because the surgeons	
12	Q. So the authors saw a connection between	12	were basically some were looking for it, some	
13	retraction and recurrence, correct?	13	weren't. That's basically what that says, correct?	
14	A. That's what they're stating.	14	A. It just means that it was not systematically	
15	Q. And, actually, in the left-hand column, the	15	looked at. It doesn't necessarily mean that surgeons	
16	very first sentence in the left-hand column at the	16	weren't looking for it, but it may have been that they	
17	top, for 15 patients, 2.2%, vaginal expositions, which	17	weren't if they were, they weren't noting it. It	
18	is an exposure, correct?	18	seemed like there was not a prospective decision to go	
19	A. Correct.	19	ahead and make that be an important measurement that	
20	Q. Were combined with prosthetic retractions.	20	was going to be documented.	
21	This suggests a statistical link between the two.	21	Q. Do you think that in any study of the TVM	
22	So they saw a statistical correlation	22	procedure or the Prolift® where safety is being looked	
23	between retraction and exposure, correct?	23	at or even recurrence is being looked at, that one of	
24	A. I don't know if they saw it or not. They	24	the things that should be a part of the protocol is to	
	said it suggested.	25	identify contraction/retraction of the mesh?	
			•	
				╝
	Page 403		Page 405	1
1	Page 403 Q. Go to the next page, 454. On Page 454 look	1	Page 405 A. Well, you can't do that in a retrospective	
1 2		1 2		
	Q. Go to the next page, 454. On Page 454 look		A. Well, you can't do that in a retrospective	
2	Q. Go to the next page, 454. On Page 454 look at the third to the bottom paragraph, starts out at a	2	A. Well, you can't do that in a retrospective study, and that's what this is.	
2 3	Q. Go to the next page, 454. On Page 454 look at the third to the bottom paragraph, starts out at a short review.	2 3 4	A. Well, you can't do that in a retrospective study, and that's what this is.Q. How about in a prospective study?	
2 3 4 5	Q. Go to the next page, 454. On Page 454 look at the third to the bottom paragraph, starts out at a short review.A. Okay.	2 3 4	A. Well, you can't do that in a retrospective study, and that's what this is.Q. How about in a prospective study?A. I think that's an important data point to	
2 3 4 5	 Q. Go to the next page, 454. On Page 454 look at the third to the bottom paragraph, starts out at a short review. A. Okay. Q. A short review confirms that the incidence 	2 3 4 5	A. Well, you can't do that in a retrospective study, and that's what this is.Q. How about in a prospective study?A. I think that's an important data point to look at.	
2 3 4 5 6	 Q. Go to the next page, 454. On Page 454 look at the third to the bottom paragraph, starts out at a short review. A. Okay. Q. A short review confirms that the incidence of prosthetic expositions, which is exposures, 	2 3 4 5 6	 A. Well, you can't do that in a retrospective study, and that's what this is. Q. How about in a prospective study? A. I think that's an important data point to look at. Q. At the very bottom of that column, the left 	
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	Confidential - Subject to Stipula	LCI		
	Page 406			Page 408
1	complication to age or menopausal status.	1		
2	Q. Let's look at the conclusion to this article	2	and when I look at the literature of comparative data,	
3	by Caquant, et. al.	3	that when other reconstructive procedures such as	
4	They indicate in the first paragraph, cure	4	native tissue repairs are done, there's a similar	
5	of genital prolapse by interposing synthetic	5	shortening of the vagina.	
6	prosthesis in vaginal root is reliable and easily	6	So if it was just because of mesh	
7	reproduced.	7	contraction, if that was the only reasoning there was	
8	See that?	8	shortening, why would you see it in procedures where	
9	A. Reproduced, yes.	9	mesh was not placed?	
10	Q. Then they say, however, the present study	10	Q. Well, you could have mesh retraction or mesh	
11	shows a relatively high incidence of late postsurgical	11	contraction rephrase.	
12	complications.	12	Mesh contraction can occur and cause	
13	Do you see that?	13	symptoms for the patient but not cause vaginal	
14	A. Yes.	14	shortening, correct?	
15	Q. So they're saying that with regard to	15	A. I don't know.	
16	complications, at least in this study of 684 patients,	16	Q. Have you ever read any studies to that	
17	they term the complication rate, postsurgical	17	effect? I just showed you one, right?	
18	complication rate as relatively high, correct?	18	A. Again, so when they called it a contraction,	
19	A. They term it that way, yes.	19	how do they know it's a contraction? I don't know how	
20	Q. Further down, the authors indicate, the very	20	they define that. I don't know how they measured it.	
21	bottom of the next paragraph, symptomatic prostatic	21	They just called they just said these people had a	
22	retractions may be of handicap with pelvic pain,	22	contraction.	
23	dyspareunia, dyschezia.	23	Q. Have you ever seen any articles where	
24	You see that?	24	contraction has been measured, where doctors have	
25	A. Yes.	25	actually tried to objectively verify that contraction	
	Page 407			Page 409
1	Page 407 O So they're saying that when there's a	1	was occurring?	Page 409
1 2	Q. So they're saying that when there's a	1 2	· ·	Page 409
2	Q. So they're saying that when there's a retraction of the mesh as a result of the scar	2	A. I've looked at studies that try and look at	Page 409
2 3	Q. So they're saying that when there's a retraction of the mesh as a result of the scar formation around it, that can cause pelvic pain,	2 3	A. I've looked at studies that try and look at that question, yes.	Page 409
2 3 4	Q. So they're saying that when there's a retraction of the mesh as a result of the scar formation around it, that can cause pelvic pain, dyspareunia and dyschezia, correct? That's what	2 3 4	A. I've looked at studies that try and look at that question, yes. Q. Have you seen any studies where that was	Page 409
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	Confidential - Subject to S	_			
		Page 410			Page 412
1	A. No.		1	Q. Who are they?	
2	Q. Would it surprise you to know that he had		2	A. I believe those are I know Jacquetin and	
3	written other articles where he actually confirmed		3	I believe Fatton are members of the TVM group.	
4	that ultrasounds do show the retraction of the mesh?		4	Q. Jacquetin is actually the person who was the	
5	A. No, it would not surprise me.		5	leader of the French TVM group, correct?	
6	Q. Would it surprise you to know that he found		6	A. That's my understanding.	
7	that ultrasound shows retraction of mesh earlier, and		7	Q. Have you ever seen this article before?	
8	then when he started apparently working with AMS,		8	A. Not that I recall.	
9	then, all of a sudden, his article said, no, I don't		9	Q. Let's go to the second page, Page 475, and	
10	see a retraction; would that be surprising to you?		10	the first full paragraph in the left column starts	
11	MR. SNELL: Objection, form.		11	"between," you see that?	
12	THE WITNESS: That's a lot of		12	A. Yes.	
13	suppositions.		13	Q. The article starts off with that paragraph	
14	BY MR. SLATER:		14	says, "Between 2000 and 2005 our team participated in	
15	Q. It's a pretty straightforward supposition.		15	the development of the tension-free vaginal mesh	
16	Would that surprise you if a relationship with		16	technique," and that's the technique that became the	
17	industry caused him to suddenly come out with an		17	Prolift®, correct?	
18	article that contradicted what he had said in a prior		18	A. Yes.	
19	article?		19	Q. And the work of that team, the French TVM	
20	A. It would surprise me if that was the reason		20	group, you believe is very important in understanding	
21	that he falsified his findings.		21	the potential risks and benefits of the Prolift®,	
22	Q. Are you familiar with other literature with		22	correct?	
23			23	A. Correct.	
24	other than the Dietz article?		24	Q. In the next sentence they say, "Over time it	
25	A. I'm not.		25	appeared that mesh retraction was probably a	
				appeared and mean remaining was productly a	
- 1					
		Page 411			Page 413
1	Q. Did you make any effort to read any other	Page 411	1	contributing factor to recurrence, postoperative pain	Page 413
1 2	Q. Did you make any effort to read any other articles besides that one?	Page 411	1 2		Page 413
	• • • • • • • • • • • • • • • • • • • •	Page 411		contributing factor to recurrence, postoperative pain	Page 413
2	articles besides that one?	Page 411	2	contributing factor to recurrence, postoperative pain and dyspareunia."	Page 413
2	articles besides that one? A. In regards to ultrasound?	Page 411	2	contributing factor to recurrence, postoperative pain and dyspareunia." You see that sentence?	Page 413
2 3 4 5	articles besides that one? A. In regards to ultrasound? Q. Yeah.	Page 411	2 3 4	contributing factor to recurrence, postoperative pain and dyspareunia." You see that sentence? A. I do.	Page 413
2 3 4 5	articles besides that one? A. In regards to ultrasound? Q. Yeah. A. I've looked at other articles on ultrasound,	Page 411	2 3 4 5	contributing factor to recurrence, postoperative pain and dyspareunia." You see that sentence? A. I do. Q. So the French TVM group felt that mesh	Page 413
2 3 4 5 6	articles besides that one? A. In regards to ultrasound? Q. Yeah. A. I've looked at other articles on ultrasound, I just can't quote them to you.	Page 411	2 3 4 5 6	contributing factor to recurrence, postoperative pain and dyspareunia." You see that sentence? A. I do. Q. So the French TVM group felt that mesh retraction was a real phenomenon and that it was	Page 413
2 3 4 5 6 7	articles besides that one? A. In regards to ultrasound? Q. Yeah. A. I've looked at other articles on ultrasound, I just can't quote them to you. Q. Why didn't you cite those other articles?	Page 411	2 3 4 5 6 7	contributing factor to recurrence, postoperative pain and dyspareunia." You see that sentence? A. I do. Q. So the French TVM group felt that mesh retraction was a real phenomenon and that it was probably a contributing factor to recurrences of	Page 413
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Page 416 - women who had the TVM technique performed on them? 2 A. I. Know that loss of people think it's a real 3 phenomena, and I am not disputing that they feed that 4 way. 5 O. My question is whether you knew that 5 bour and potentially other members of the Frunch 7 TVMg group had that viewpoint? Did you know that 8 before I just showed this to you? 9 A. No. 10 O. I think you said earlier you have a great 10 deal of respect for the Frunch TVM group is knowledge 20 of the presculator that became the Prolifith. 11 Did I understand you correctly? 12 O. Do you feel that way? 13 A. Too the collect what? 14 A. I don't early to have a great deal of the performed by the transport of the promother of think provided and dyspaceunia. If 15 Q. Do you feel that way? 16 A. I do not all way a great deal of respect for 17 Did I understand you correctly? 18 Professor Inceptin in other other members of the TVM 19 proporting regard to that the performed to the transport of the promother of the transport of the promother o		Confidential - Subject to Stipula			
2 A. Hanow that lots of people think it's a read 3 phenomena, and I am not disputing that they feel that 4 way. 5 Q. My question is whether you knew that 6 Jacquetin and potentially other members of the French 7 TVM group had that viewpoint? Did you know that 8 before? Just showed this to you? 9 A. No. 9 Sought of the provided of the problem of the French 10 Q. I think, you said earlier you have a great 11 deal of respect for the French TVM group's knowledge 12 of the procedure that became the Problidio. 12 Problidio mechins a contributing or causative factor to the transport of the French TVM group is knowledge 13 of the procedure that became the Problidio. 14 A. I don't creatl saying that, but 15 Q. Do you feel that way? 15 Q. Do you feel that way? 16 A. I do feel what? 17 Q. That you have a great deal of respect for the TVM 18 provided that the problem of the TVM 19 procedure that became the remembers of the TVM 20 procedure that became the wholl members of the TVM 21 provided that way you then the problem of the TVM 22 provided that way you then the problem of the TVM 23 provided that way you then the problem of the TVM 24 provided that way you the group with regard to their understanding of the TVM 25 provided that became the Problidio procedure? 26 Q. That you have a great deal of respect for them in 27 Q. That you have a great deal of respect for them in 28 great deal of respect for the TVM 29 group with regard to their understanding of the TVM 20 group with regard to their understanding of the TVM 21 A. I have a great deal of respect for them in 22 great deal of respect for the TVM 22 feel was suggested that should be respected and 23 done a lot of studying on it, so — and I think that 24 dry as surgeoses that should be respected. 25 problem in an of the dry think that 26 great of that seel in impact on your optinions to see 27 seatence, does not in impact on your optinions to see 28 sentence, does not in impact on your optinions to see 29 centere, does not in inpact on your optinions to see 30 that		Page 414			Page 416
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4 vay. 4 question? 5 Lacqueria and potentially other members of the French 5 Lacqueria and potentially other members of the French 7 TVM group had that viewpoint? Did you know that 8 before I just showed this to you? 9 A. No. 10 Q. I think you said earlier you have a great 11 dead of respect for the French TVM group's knowledge 12 of the procedure that became the Prolitifol. 12 Prolitifol mesh is a contributing or causarive factor to 13 Did I understand you correctly? 14 A. I don't nevel asysing that hat — 15 Q. Do you feel that way? 15 you disagree with that? 16 A. I do feel what? 17 A. I to easy great deal of respect for 18 processor Jacqueria and the other members of the TVM 19 procedure that became the Prolitifol procedure? 20 Tecurinesc, postporearive pain and dysparential, if 21 Jack who believe that tresh eteraction of 22 recurrence, postporearive pain and dysparential, if 23 A. No. 24 Lot feel what? 25 you disagree with that? 26 Jack is to know that they have a great deal of respect for 27 A. I twee a great deal of respect for 28 Professor Jacqueria and the other members of the TVM 29 procedure that became the Prolitifol procedure? 20 Regard to that specific thing. I know that they have 21 A. A. Thave a great deal of respect for them in 22 regard to that specific thing. I know that they have 23 done a lot of studying on it is so—and I dink that 24 they are surgeons that should be respected and 25 research that should be respected. 26 Well, now that I'm showing you this 27 emerited. But you ever considered using ultrasound? 28 remember, does that impact on your opinions to see 30 that Professor Jacqueria in one of the authors in the 4 article that states that mesh retraction is probably a 5 countibuting english right now? 29 Q. Well, asow that I'm showing you this 29 emerited, better the recurrence, 29 Q. Right. 20 Q. So so dispute that mesh erraction is 21 probably a contributing factor to recurrence. 21 postoperative pain and dysparential or— 22 prostopera	2		2		
5 Q. My question is whether you knew that 5 Jacquetin and potentially other members of the French 7 TVM group hat that viscoping 105 day on know that 7 TVM group hat that viscoping 105 day on know that 8 before I just showed this to you? 9 A. No. 10 Q. I think you said earlier you have a great 11 deal of respect for the French TVM group's knowledge 12 of the procedure that became the Prolific®. 13 Did I understand you correctly? 14 A. I don't recall saying that, but - 15 Q. Do you feel that way? 15 Q. Do you feel that way? 16 A. I do feel what? 17 Q. I that you have a great deal of respect for 18 Professor Jacquetin in the other members of the TVM 19 group with regard to their understanding of the TVM 19 procedure that became the Prolific® procedure? 20 Question that became the Prolific® procedure? 21 A. I have a great deal of respect for them in 22 regard to that specific thing. I know that they have 23 done a lot of studying on it, so — and I think that 24 they are surgoons that should be respected and 25 research that should be respected and 26 and dyspareunia? 27 Q. Well, now that I'm showing you this 28 tentence, does that impact on your opinions to see 30 that Professor Jacquetin is one of the authors in the 31 article that stream that provide pain in the professor procedure? 32 Q. Right. 33 A. No. 34 A. No. 35 Contributing factor to recurrence, poatoperative pain 36 A. No. 36 Contributing factor to recurrence, poatoperative pain 37 A. See sit change anything about your 38 pour suggested that you should? 39 Q. Os it dones't change anything about your 30 Q. Disyou object that mesh retraction is 31 that Professor Jacquetin in one of the authors in the 32 contributing factor to recurrence, poatoperative pain 38 both terraction in all their articles. 39 Q. Os it dones't change anything about your 30 Q. Disyou dispute that mesh retraction is 31 that Professor Jacquetin is one of the authors in the 32 contributing factor to recurrence, poatoperative pain 39 probably a contributing factor to recurrence. 30 Q. Do		phenomena, and I am not disputing that they feel that	3	*	
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	Confidential - Subject to Stipula	LLI	on and order or confractional.	LCY
	Page 418			Page 420
1	whether the mesh is a possible cause before the	1	Do you see that?	
2	surgeon is going to operate and do potentially morbid	2	A. Yes.	
3	surgery on the woman. Let's talk about that	3	Q. At the bottom of the page, Page 478, it	
4	situation.	4	says, "Mesh retraction, also known as mesh shrinkage	
5	A. Okay.	5	or mesh contraction, can be defined by a reduction of	
6	Q. In that context would ultrasound be helpful?	6	the surface area of the original implanted mesh."	
7	A. It might be.	7	Is that a statement you agree with or	
8	Q. You haven't thought about that question one	8	disagree with?	
9	way or the other?	9	A. I think that is a statement that makes	
10	A. I think about I don't know that I've	10	sense.	
11	thought specifically about that question.	11	Q. They then say, "It has been shown that, in	
12	Q. In Results section on next column down at	12	the abdominal wall, mesh retraction is related to the	
13	the bottom, this article defines that "between	13	degree of tissue inflammation around the mesh after	
14	March 2005 and August 2006, 125 consecutive patients	14	implantation."	
15	were operated on in our unit for symptomatic POP-Q	15	Do you see that?	
16	Stage 2-4 anterior and/or posterior vaginal wall	16	A. I do.	
17	prolapse with the Prolift® procedure."	17	Q. And do you have an understanding of why in	
18	You see that?	18	an article about the use of mesh for prolapse an	
19	A. I do.	19	article with regard to mesh retraction in the	
	Q. So that's telling us how many patients and		abdominal wall would be cited?	
20		20	A. Yes, because it's a similar type of	
21	some general information about who they were and that	21		
22	they all got Prolifts®, correct?	22	procedure.	
23	A. Correct.	23	Q. And they cite it says reference 14, and that	
24	Q. Let's go to the next page. In the	24	is an article that was authored by Klinge,	
25	right-hand column, we get some information about the	25	K-l-i-n-g-e, Klosterhalfen and several other people	
_	Page 419			Page 421
	rage 419			Fage 421
1	outcomes at three months, which started in the left	1	named "Foreign body reaction to meshes used for the	rage 421
1 2		1 2		rage 421
	outcomes at three months, which started in the left			rage 421
2	outcomes at three months, which started in the left column but goes over to the top and says that 9, which	2	repair of abdominal wall hernias," correct?	rage 421
2 3	outcomes at three months, which started in the left column but goes over to the top and says that 9, which was 9.9% of the patients had vaginal mesh exposure at	2 3	repair of abdominal wall hernias," correct? A. Correct.	rage 421
2 3 4	outcomes at three months, which started in the left column but goes over to the top and says that 9, which was 9.9% of the patients had vaginal mesh exposure at three months, correct?	2 3 4	repair of abdominal wall hernias," correct? A. Correct. Q. So they're citing to Klinge, Klosterhalfen,	rage 421
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Page 422 Page 424 1 field? 1 correct? 2 A. Let me look at the reference. I'm not 2 A. You want to represent the reality of life, 3 recalling that I'm familiar with this article. 3 as you see it, yes, absolutely. Q. The authors of this article in talking about Q. And you don't want to give a biased, 4 5 Tunn talk about the fact that in that study, the one-sided perspective; you want to give both sides to 6 authors compared the initial length of implanted mesh be fair and balanced, correct? 7 and the sonographically measured mesh length six weeks MR. SNELL: Well, I'm going to object 8 postoperatively observing a decrease in the mesh to form of that. length of 60% for anterior meshes and 65% for BY MR. SLATER: posterior meshes. Q. When you author articles, don't you want to 10 10 11 You see that? be fair and balanced to make sure you take into 11 A. I do. account both sides? 12 Q. Is that -- is this an article that you're A. The point of the time to rethink article was 13 13 14 familiar with? Are those statistics you're familiar to specifically present a counterpoint to, in my opinion, a biased viewpoint. It was not a scientific 15 with? 16 A. No. 16 article. Q. This article that I'm showing you now with a Q. The rethink article was meant to give a 17 17 18 reference to Tunn, is this providing information to counterpoint; meaning you thought the FDA had been 19 you that is essentially new to you with regard to the 19 one-sided, so you were trying to give the other side use of ultrasound where studies have actually, of the story? 20 according to the studies, documented mesh retraction? 21 A. Correct. A. You know, I did a debate with Don Ostergard 22 22 Q. So you weren't intending to be scholarly in 23 at a course, I think it was last summer, and, you that sense; you were trying to just give the other 24 know, I have seen other studies, I just couldn't side of the story? 25 recall any particular exact study. So it's not that A. I was trying to base all my arguments based 25 Page 423 Page 425 1 I'm not aware that there are people out there that 1 on evidence that I found in the literature that's in 2 have shown different findings than what I quoted in 2 the thing, but in no way did I purport that I had 3 regard to the article I reference in the time to 3 performed a systematic review on this and these were 4 rethink article. 4 my opinions. Q. Well, in the time -- when you authored the Q. And you weren't intending to be fair and 6 time to rethink article, you only referred to the 6 balanced in providing your viewpoint; you were trying 7 Dietz article with regard to ultrasound, correct? to find -- you were trying to provide your side of the 8 A. Yes. It was not a systematic review, that's story? 8 A. I was trying to provide balance to the 9 correct. 9 10 Q. I'm showing you some literature from 10 story Jacquetin and his group and other articles they cited. Q. So you felt the FDA had gone one way, so you 11 11 12 Do you feel, in retrospect, that you 12 were trying to balance that by giving the other probably didn't give a balanced view of the literature 13 viewpoint? 14 with regard to ultrasound and the ability to image A. Well, I wanted to present data that I 15 retraction? believed in, and, yes, I mean, the whole point of the 16 MR. SNELL: Objection, form. article was to say, we think that there's some bias in THE WITNESS: I'd have to review the the way all this is going down, so to speak, and we 17 18 literature before I could make that statement in a would like people to see another side of things, 18 19 systematic way. 19 absolutely. 20 BY MR. SLATER: 20 Q. The -- I think you said a moment ago, the Q. You would agree with me that in any article time to rethink article was not meant to be a 21 21 scholarly article, correct? 22 describing anything in the literature, and we're 22 23 talking about, you know, pelvic mesh in the Prolift® 23 MR. SNELL: Objection, misstates. 24 here, but in any context, you want to be fair and 24 THE WITNESS: I think you said that. I 25 balanced in providing information in the journal, didn't say that.

Page 426 Page 428 1 BY MR. SLATER: So this article was focused only on, as they 2 said before, what they're calling mid -- what they're 2 When you wrote the time to rethink article, you didn't write it in a -- well, rephrase. 3 calling immediate morbidity is what happened either at 3 The time to rethink article, was it peer 4 the time of the procedure or what manifested in the 4 hospital, correct? 5 reviewed? A. Yes. A. Correct. 6 7 Q. By who? Q. And if you go to the next page, they found 8 A. By the editors of the International that what they termed minor complications -- rephrase. Urogynecology Journal. On Page 307 Dr. Altman says, "Close to 15% 9 Q. Did you have to make any changes to it? of our patients experienced what we characterized as 10 10 11 A. Yes. minor complications. Although not life threatening, 11 Q. What? 12 such complications may have considerable impact on 12 A. If you provide me the article, I might be quality of life and daily function. Prospective 13 13 14 able to recall some changes. I know one of the things studies extending beyond the operative hospital stay I had to say was that the -- I think the very article are therefore needed to clarify how minor that we're referring to, it had not been -- it would complications attributed to the surgical procedure, be much easier for me to give the answer to that such as groin pain, buttock pain, defecation 18 question if I could look at the article. difficulties, urinary urgencies and bladder emptying 19 19 Q. That's fine. We'll come back to it. difficulties, progress over time." MR. SNELL: Okay. 20 First of all, do you agree that the types of 20 BY MR. SLATER: complications described, even if you term them minor 21 21 Q. Show you an article marked as Exhibit 665 because they're not life-threatening, can have 22 22 23 titled "Perioperative Morbidity Using Transvaginal 23 considerable impact on the quality of life and daily 24 Mesh in Pelvic Organ Prolapse Repair" authored by 24 function for a woman? 25 Daniel Altman, Christian Falconer in February 2007. A. Yes. 25 Page 427 Page 429 Are you familiar with this article? Q. And do you agree that as of the time of this 1 A. Yes. 2 article, February 2007, there was a need for 2 3 Q. Is Dr. Altman somebody whose viewpoints you prospective studies and, in fact, even though it's not stated here, prospective long-term studies to gather 4 respect? A. Yes. information about how the types of complications 5 6 Q. If you could turn to Page 307 of this 6 listed here could progress over time and impact on a 7 article. Actually, before you do that, let's just set 8 a couple of parameters. This article studied short A. There's always need for more study of any 8 9 term what they called perioperative complications, 9 procedure. 10 meaning complications that were documented during the 1.0 Q. In the next column, top, fifth line down, 11 procedure or during the hospital stay following the they say, "Finally, a surgical procedure may be 11 12 procedure, correct? It's on Page 304, top right universally accepted when the magnitude of its 13 corner. benefits outweighs the risks. To decide whether 14 A. Correct. transvaginal mesh procedures are beneficial in 15 Q. And this involved the use of the Prolift® comparison with traditional suture techniques, 16 and just below it says 248 women, correct? prospective comparative studies are necessary." 17 17 You agree with that statement, correct? A. Correct. MR. SNELL: Objection. Which one? I Q. Now, let's turn to the Results, that's Page 18 18 19 306, first of all, the Discussion section. The very 19 thought you read a couple statements there. 20 bottom of that first paragraph Discussion it says, BY MR. SLATER: 20 "The present study focuses on immediate morbidity Q. The second sentence, do you agree with that 21 22 caused by the surgical technique rather than mid-to 22 statement? long-term complications such as rejection, erosion and A. "To decide whether transvaginal mesh 23 infections typically ascribed to the biomaterials procedures are beneficial in comparison with themselves." traditional suture techniques, prospective comparative

	Confidencial - Subject to Scipula			
	Page 430			Page 432
1	studies are necessary."	1	A. I agree with the fact that they said results	
2	Q. Do you agree that that was a true statement	2	may not be directly applicable. It doesn't mean you	
3	when this article was written, February 2007?	3	can't draw any conclusions from it.	
4	A. Again, I will state that the more data you	4	Q. The authors conclude at the end of this	
5	have, the better it is.	5	article, "Caution is advised until large-scale	
6	Q. At the bottom of Page 307, you can read it	6	long-term prospective safety studies describing	
7	to yourself, it says "much of the current knowledge."	7	biocompatibility are available."	
8	Do you see that?	8	Do you think that they are correct that as	
9	A. I do.	9	of February 2007 when they published this article, one	
10	Q. That paragraph basically talks about TVT®	10	needed to exercise caution?	
11	and SUI slings.	11	A. One always needs to exercise caution in	
12	Do you see that?	12	operating on patients.	
13	A. I do.	13	Q. Well, especially here where there were no	
14	Q. And then it talks about the fact that "it	14	large-scale long-term prospective safety studies as of	
15	is, however, important to consider the different	15	that time, was that an additional reason to be	
16	anatomical conditions associated with pelvic organ	16	cautious?	
17	prolapse surgery."	17	A. I wouldn't say it's additional. I mean,	
18	Do you agree with that, that if you're going	18	there weren't lots of long-term studies on anterior	
19	to try to compare TVT® with	19	colporrhaphy when people were doing that with a lot of	
20	A. Yes, they're not the same procedure.	20	regularity, but you still did it because you had to	
21	Q. Okay. And they say, "Compared with	21	treat patients the best way you thought possible.	
22	suburethral tapes, biomaterials used at pelvic organ	22	Q. Anterior colporrhaphy was not developed by a	
23	prolapse repair increase the biomaterial load	23	company, was it?	
24		24	A. No, it was not.	
	mesh."	25	Q. It was developed by surgeons who were	
23	inesii.	23	Q. It was developed by surgeons who were	
	Page 431			Page 433
1	Page 431 Would you agree with that statement?	1	working to develop methods to treat pelvic floor	Page 433
1 2		1 2	working to develop methods to treat pelvic floor A. Correct.	Page 433
	Would you agree with that statement?			Page 433
2	Would you agree with that statement? A. Again, I'm not overly familiar with the term	2	A. Correct.	Page 433
2 3	Would you agree with that statement? A. Again, I'm not overly familiar with the term biomaterial load, but if there is a biomaterial load	2 3	A. Correct. Q issues, correct?	Page 433
2 3 4	Would you agree with that statement? A. Again, I'm not overly familiar with the term biomaterial load, but if there is a biomaterial load on a TVT® sling, I would definitely agree that the	2 3 4	A. Correct.Q issues, correct?A. Correct, sorry, yes.	Page 433
2 3 4 5	Would you agree with that statement? A. Again, I'm not overly familiar with the term biomaterial load, but if there is a biomaterial load on a TVT® sling, I would definitely agree that the biomaterial load on a Prolift® is going to be larger.	2 3 4 5	A. Correct.Q issues, correct?A. Correct, sorry, yes.Q. And that's just part of the advance of	Page 433
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	confidencial publices to being		_
	Page 43		Page 436
	definitely some truth to that.		and I clarified it. You could read it back again.
2	BY MR. SLATER:	2	(The court reporter read back the
3	Q. When a company like Ethicon is involved in	3	record as requested.)
4	developing a procedure like the Prolift® and intends	4	MR. SNELL: Objection, form.
5	to sell it for money	5	THE WITNESS: No.
6	A. Yes.	6	BY MR. SLATER:
7	Q the company has an independent obligation	7	Q. Does a company like Ethicon that is
8	to make sure that the company is cautious and is	8	intending to market a medical device have an
9	careful and makes sure that there are enough studies	9	obligation to study that medical device before
10	so the company can provide reliable information to	10	marketing it?
11	physicians and patients about that?	11	A. From whose viewpoint?
12	A. I'm agreeing with everything you said except	12	Q. From your viewpoint as an expert on behalf
13	the "enough studies." I think that the duty of a	13	of Ethicon.
14	company that's going to produce a medical device,	14	A. Does it have to study the product? It has
15	their duty is to try to provide more benefit than harm	15	to so here's the thing, medical devices are often
16	to the patients in whom this device is going to be	16	changed as time goes by, okay. What constitutes a big
17	used.	17	enough change that you have to do a whole lot more
18	Q. Does did Ethicon have an obligation to	18	study, that's a very subjective question.
19	make sure that it had adequate data to be able to	19	So, for instance, monofilament, large pore
20	reliably provide warnings and information to	20	polypropylene mesh have been used in human beings for
21	physicians and patients about the risks and benefits	21	decades, okay, so that plays into the answer, okay,
22	of the Prolift® before they put it on the market?	22	where you're leaving polypropylene mesh in patients.
23	MR. SNELL: Objection, form.	23	That's something that's been done for many, many
24	THE WITNESS: You'd have to repeat that	24	years.
25	question.	25	Q. The Prolift® system involved leaving
	Page 43.	5	Page 437
	e e e e e e e e e e e e e e e e e e e		e e
1	MR. SLATER: Could you read that back,	1	polypropylene mesh inside a woman's body but in a
1 2	MR. SLATER: Could you read that back, please.	1 2	polypropylene mesh inside a woman's body but in a shape that hadn't been used, with instruments that
2	please.	2	shape that hadn't been used, with instruments that
2 3	please. (The court reporter read back the	2	shape that hadn't been used, with instruments that hadn't been used and with a procedure that was a new
2 3 4	please. (The court reporter read back the record as requested.)	2 3 4	shape that hadn't been used, with instruments that hadn't been used and with a procedure that was a new procedure, correct?
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	Page 438			Page 440
1	Q. Do you know whether there were any	1	where mesh in this type of a quantity had to be	
2	differences between the instruments used at the	2	removed in this fashion from a Prolift® patient?	
3	various centers?	3	A. I've never done a surgery where I removed	
4	A. I do not.	4	that much material, correct.	
5	Q. Do you know if there were variations to any	5	Q. Have you ever treated a patient who had that	
6	extent between the procedures that were being	6	or a similar amount of mesh removed?	
7	performed at the various centers in the TVM study?	7	A. I don't know. I don't recall.	
8	A. Do you mean concomitant procedures?	8	Q. Just above that, those two pictures, there's	
9	Q. No, the procedure, the TVM procedure that	9	a sentence that starts just three lines up, "it is	
10	was being used, were there any variations between	10	important." Do you see that?	
11	let's start with the French procedure in the US, were	11	A. Yes.	
12	there any differences?	12	Q. "It is important to remember that a	
13	A. Not to my knowledge.	13	percentage of patients who undergo pelvic	
14	Q. Did you ever look at that issue to see if	14	reconstructive surgery with vaginally placed mesh will	
15	there were any even minor differences between what the	15	have life-changing complications. Moreover, whereas	
16	surgeons were doing either between the French and US	16	minor complications such as small vaginal mesh	
17	groups or even from center to center?	17	erosions are simple and easy to manage, incapacitating	
18	A. I don't know how I could have looked at	18	pelvic pain, dyspareunia and large-scale erosions can	
19	that, apart from what I read in the articles on TVM.	19	be exceedingly complex and not easily resolved."	
20	Q. Have there been any patients, to your	20	Is that a true statement with regard to the	
21	knowledge, who you place Prolifts® in who then left	21	Prolift®?	
22	your care to go to other doctors to treat their	22	MR. SNELL: Objection, form, which one	
23	complications?	23	of the couple sentences.	
24	A. I can very specifically think of a couple of	24	BY MR. SLATER:	
25	cases of sling patients that did that. If there are	25	Q. That entire paragraph, does that paragraph	
25	cases of string patients that the that. If there are	25	Q. That entire paragraph, does that paragraph	
	Page 439			Page 441
1	Page 439 patients who had Prolift® who did that, I would not be	1	apply to the Prolift®?	Page 441
1 2		1 2	apply to the Prolift®? MR. SNELL: Objection, form.	Page 441
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	Page 442		O Vou don't kn?	Page 444
	So I agree with that in regards to transvaginal mesh	1		
2	procedures, and I do have experience in treating patients like that.	3		
3	Q. Just to be very clear and clean, with regard	4		
4	to this portion of the article on Page 529 to 530 that		besides what you've seen, so do you have an opinion	
5	starts out, "It is important to remember that a	5	one way or the other as to whether that's true for the	
6	percentage of patients who undergo pelvic	6	- 44 - 4	
7	reconstructive surgery with vaginally placed mesh will	7		
8	have life-changing complications. Moreover, whereas	8	A. Here's the problem, you can have incapacitating pain from a surgery, so if you have a	
9	minor complications such as small vaginal mesh	9	prolapse, if you have a Prolift® procedure done and	
10	erosions are simple and easy to manage, incapacitating	10		
11	pelvic pain, dyspareunia and large-scale erosions can	11 12		
12	be exceedingly complex and not easily resolved."			
13	To be very clear, with regard to the	13		
14	Prolift®, is what I just read applicable?	14	Q. Well, if a woman only had a Prolift®	
15	* **	15	•	
16	MR. SNELL: Objection, form. THE WITNESS: Okay. Can we go sentence	16	procedure and didn't have anything else, then the surgery in her pelvis was the Prolift® procedure,	
17	by sentence because you're asking me to agree or not	17		
18	agree to multiple sentences; is that fair enough?	18		
19	BY MR. SLATER:	19	Q. Do you have an opinion as to whether that	
20		20		
21	Q. Sure.	21		
22	A. So "it is important to remember that a percentage of patients who undergo pelvic	22	•	
23		23	A. It could be. It can be for any surgery,	
24	have life-changing complications."	25	yes. Q. Well is it true for the Prolift®?	
25	have me-changing complications.	25	Q. Well is it true for the Fronties:	
	Page 443			Page 445
1	Page 443 Q. Is that a true statement with regard to the	1	A. It's theoretically possible, yes.	Page 445
		1 2		Page 445
	Q. Is that a true statement with regard to the		Q. Do you know whether the people in medical	Page 445
2 3	Q. Is that a true statement with regard to the Prolift®?	2	Q. Do you know whether the people in medical affairs believe that this section of this article that	Page 445
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Page 446 Page 448 1 say that the Prolift® was uniquely responsible for A. I am happy to look at the IFU and state 2 that complication is hard to say. 2 exactly what it says. I think it mentions erosions. 3 MR. SLATER: Move to strike. Q. It mentions erosion. Does it point out to 4 BY MR. SLATER: 4 surgeons in the IFU that large-scale erosions from the Q. Here's my question: If medical affairs knew Prolift® can be exceedingly complex and not easily 5 6 that some women who would get the Prolift® put in 6 resolved with treatment? 7 their body would have complications as severe as what A. It certainly does not say those words, as 8 is described in what we just read from Page 529 to you and I know. 9 Page 530 of this article, you would agree with me that Q. The information found on Page 529 and 530 10 Ethicon, if they knew that on the day of launch, that here with regard to these very serious complications, 11 this is the kind of information that they needed to does the patient brochure for the Prolift® provide warn about in the IFU and warn patients about in the that type of information to patients? A. I'd have to review it. patient brochure, correct? 13 14 A. I think that they did. 14 Q. I almost gave you someone else's notes that 15 MR. SNELL: Objection, form. Go ahead. 15 I don't know what they say. 16 THE WITNESS: I think that they did 16 THE WITNESS: You might want to try warn people of that in the IFU. opening that door again. BY MR. SLATER: 18 18 MR. SNELL: Yeah, that's a good idea. 19 Q. You think that what I just read there that 19 MR. SLATER: I got a pair of shorts in 20 that is warned of in the IFU? my car, if you want. 20 THE WITNESS: I do too. 21 A. I think that they warn of the things that 21 22 can lead to that complication. BY MR. SLATER: 22 23 Q. Do you think that IFU for the Prolift®, and 23 Q. Have you looked at the patient brochure to we're talking about the first IFU, obviously, you try to answer that question? 25 understood that, right? A. I'm sorry. I didn't realize that's what you 25 Page 447 Page 449 A. Yes. 1 were asking me to do. I thought you were checking 1 Q. Warns physicians that patients who get the 2 your e-mail. Okay. 3 Prolift® put in their body can end up with So the question is? 4 incapacitating pelvic pain? Q. Does the patient brochure warn patients, and 5 the patient brochure I gave you is marked Exhibit 935, A. I think it states that it can lead to -- I'd 6 have to read it again, but I think it says scarring, 6 correct? damage to surrounding organs, all of those things can 7 Correct. lead to pelvic pain. Q. And that's the first patient brochure that 8 Q. They don't necessarily lead to was used beginning in 2005 for the Prolift®. Does it 9 10 incapacitating pelvic pain, do they? warn patients with regard to the very serious 11 A. They do not necessarily lead to it. complications described as we've been reading from the Q. Does the IFU specifically warn of the risk bottom of Page 529 over to the top of Page 530 of the 12 13 of dyspareunia? article by Blandon, B-l-a-n-d-o-n, et. al.? 14 A. Does it use the term dyspareunia? I do not A. I can state exactly what it states. 15 believe that it does. 15 Q. Rather than you reading it to me, I'm asking Q. Does the IFU warn that large-scale erosions you are the very severe types of complications 16 from the Prolift® can be exceedingly complex and not described in this article warned about in this patient 17 17 18 easily resolved? brochure? 18 19 A. Those words are not in the IFU. 19 A. I mean, did they use the exact same words that they did in the article? I mean, that would be 20 Q. There is no description whatsoever in the 21 IFU of the complexity of some of the erosions that can quite a coincidence if they did, so let me -- can I 21 22 occur and the fact that even with intensive treatment, 22 answer your question? 23 they may not be able to be resolved, that is not 23 Q. I'm obviously not asking if they used the 24 warned about with regard to the Prolift® in the IFU, exact words, but do they warn of those types of 25 correct? complications?

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	Page 450			Page 452
1		1	Q. But you've never studied that question, and	
2		2	you can't point to anything to confirm that, correct?	
3		3	A. I have no publications on that.	
4		4	Q. Let's take a step back. Here in the patient	
5		5	brochure, Page 13, there's a heading that says "What	
6		6	are the risks?" And it says that the complications	
7		7	from the Prolift® procedure are rare.	
8	• •	8	Do you see that?	
9	If you have difficulty urinating, if you	9	A. No, I don't see that it says that. It says,	
10	have bladder or bowel injury, I think that could be a	10	"although rare, complications associated with the	
11	life-changing or life-altering no, life changing is	11	procedure include" those things, so it's saying that	
12	the term that they use complication. So that's why	12	not every complication is going to be common to the	
13	I said yes to your question.	13	procedure.	
14	Q. So you're basically saying that based on	14	Q. Let's go to the prior page, if you could,	
15	that language, you would assume that patients would	15	and we're going to read a few things together.	
16	figure out that when they read that language, that is	16	At the top of Page 10 of the patient	
17	communicating to them that the complications they can	17	brochure, it says, What is Gynecare Prolift®, and it	
18	suffer from the Prolift® can be life changing and that	18	describes that and says, "A new and revolutionary	
19	those complications can result in incapacitating	19	minimally invasive surgical procedure using Gynecare	
20	pelvic pain, dyspareunia and large-scale erosions that	20	Prolift®," and it goes on, right?	
21	can be exceedingly complex and not easily resolved?	21	A. Correct.	
22	A. I don't think that a patient brochure is	22	Q. Then if we go to the next page, when it	
23	the point of it is to explain every potential possible	23	says, "What are the risks?" It says, "All surgical	
24	thing that can happen to a patient. I think what the	24	procedures present some risks. Although rare,	
25	point of a patient brochure is is to facilitate a	25	complications associated with the procedure," and	
	Page 451			Page 453
	Page 451 discussion between the patient and her surgeon	1	that's referring back, that's the Prolift® procedure	Page 453
	discussion between the patient and her surgeon		that's referring back, that's the Prolift® procedure we're talking about, correct?	Page 453
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1	rare is in this patient brochure?	1	BY MR. SLATER:	
2	A. No.	2	Q. So other than exposure of mesh, which is a	
3	Q. Would you agree with me that it's likely	3	small risk, the rest of the complications occur	
4	that different patients would define rare differently	4	rarely; patients could read this that way, correct?	
5	as they would read this brochure?	5	MR. SNELL: Objection.	
6	A. Sure.	6	THE WITNESS: Yes, I think they could.	
7	Q. And would you agree with me that some	7	BY MR. SLATER:	
8	patients would probably read this brochure and believe	8	Q. You would agree with me that the overall	
9	that it's telling them that the complications	9	complications with the Prolift® procedure are not	
10	associated with the Prolift® procedure are rare in	10	rare?	
11	general?	11	A. Again, I have to get back into comparison to	
12	A. Again, to answer the same way, the same	12	other surgeries, so if you're saying it's rare, you	
13	question I think, I think it's referring to, well, the	13	have to have some standard for what's rare, okay. So	
14	risk of injury to blood vessels of the pelvis, that's	14	we're saying all surgical procedures have risk. So if	
15	rare. The risk of nerve damage, that's rare.	15	you're saying, okay, we're talking about a surgical	
16	Difficulty urinating, that's rare. It's not saying	16	procedure, so if you want to differentiate it from	
17	that in totality any risk from surgery is rare. It's	17	other surgical procedures, you're saying that it's so	
18	saying it's referring specifically to those	18	different than anterior colporrhaphy, so then you	
19	complications that it then lists.	19	would want to compare it, and as far as I know, the	
20	Q. Would it be a reasonable reading of this for	20	studies, comparative studies, transvaginal mesh	
21	a patient who is not a urogynecologist with your	21	procedures and native tissue repairs show that	
22	experience to read it and say, okay, what are the	22	complication rates are comparable.	
23	risks? All surgical procedures present some risks.	23	MR. SLATER: Move to strike.	
24	So, okay, the patient has been told every procedure	24	BY MR. SLATER:	
25	has some risks; patient could understand that, right?	25	Q. Is there any way for you and I to be able to	
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	Page 455		comes on discourse as to whether or not the	Page 457
1	A. Correct.	1	agree or disagree as to whether or not the	Page 457
2	A. Correct.Q. And then a patient could read this and say,	2	complications of the Prolift® procedure are rare as	Page 457
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2	done in the world in totality, yes, it would be	2		
	impossible to say exactly what rare meant in relation	3	A. I do not have any insight into what they	
4	to each of those complications.	4		
5	BY MR. SLATER:	5	MR. SLATER: Change the tape.	
6	Q. If a patient were to read this and say,	6	THE VIDEOGRAPHER: Going off the	
	complications are rare and were to read rare to mean	7	•	
8	it's something that basically almost never happens,	8	(Brief recess.)	
9	it's such a small amount of time that I don't even	9	THE VIDEOGRAPHER: We're back on the	
10	have to worry about it, if a patient read it that way	10	record. Here marks the beginning of Volume 1 in Tape	
11	because a patient defines rare to mean something that	11	8, the deposition of Dr. Miles Murphy. The time is	
12	you might see once in your life, that's what rare	12	8:53 p.m.	
13	means to this patient, that wouldn't surprise you if	13	BY MR. SLATER:	
14	some patients think that, right?	14	Q. Let's look at the patient brochure, Page 10,	
15	A. I would hope that that person, that patient	15	under where it says "What is Gynecare Prolift®?"	
16	would also have a discussion about the risks of the	16	It describes the Prolift® as a new and	
17	surgery with their physician, but, yes, absolutely, if	17	revolutionary minimally invasive surgical procedure.	
18	they read this, they might think that rare means rare.	18	You see that?	
19	Q. In the second sentence here under what are	19	A. I do.	
20	the risks where it says, "There is a small risk of the	20	Q. Do you agree that the Prolift® procedure is	
21	mesh material becoming exposed into the vaginal	21	minimally invasive?	
22	canal," if there were people within Ethicon that	22	A. I do.	
23	thought that exposure was common and that was the word	23	Q. The vaginal incisions again with the total	
24	they actually used internally, then they shouldn't	24	Prolift®, the six trocar incisions placed through the	
25	have called it a small risk, correct?	25	skin into the pelvis and then all of the dissections	
		150		70 161
	Page	459		Page 461
,	A T 41-1-1-41-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4		in ide of the higher consideration to the minimalian	
1	A. I think that when regarding risks, the term		inside of the body, you consider that to be minimally	
2	small and common would be different.	2	invasive?	
2	small and common would be different. Q. So you would agree with me if people within	2	invasive? A. I have a definition of minimally invasive	
2 3 4	small and common would be different. Q. So you would agree with me if people within Ethicon thought exposure was common, they shouldn't	2 3 4	invasive? A. I have a definition of minimally invasive that I'd be happy to give to you, if you like.	
2 3 4 5	small and common would be different. Q. So you would agree with me if people within Ethicon thought exposure was common, they shouldn't have used the word small here, right?	2 3 4 5	invasive? A. I have a definition of minimally invasive that I'd be happy to give to you, if you like. Q. Sure.	
2 3 4 5 6	small and common would be different. Q. So you would agree with me if people within Ethicon thought exposure was common, they shouldn't have used the word small here, right? MR. SNELL: Objection, form. Would you	2 3 4 5	invasive? A. I have a definition of minimally invasive that I'd be happy to give to you, if you like. Q. Sure. A. I consider minimally invasive surgery	
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2 3 4 5 6 7 8	small and common would be different. Q. So you would agree with me if people within Ethicon thought exposure was common, they shouldn't have used the word small here, right? MR. SNELL: Objection, form. Would you read that back. I missed small. (The court reporter read back the	2 3 4 5 6 7 8	invasive? A. I have a definition of minimally invasive that I'd be happy to give to you, if you like. Q. Sure. A. I consider minimally invasive surgery something that is in my field as something that is done through a transvaginal route or something that is	
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Page 462 Page 464 1 in the Prolift®, if you trace it back, was actually 1 function or improvement but actually could be sexual 2 Prolene® Soft mesh that was developed for use to treat 2 function could get worse and the patient could end up 3 hernias originally? with painful sexual intercourse; that's not A. I'm aware that it was Gynemesh® PS, which communicated, correct? had an FDA approval for use in the pelvic floor. I've A. I think I just answered that question, yes, 6 heard something about that it had previous uses, but I that's correct. don't know for sure. Q. From your perspective, is dyspareunia an Q. You don't know, as you sit here now, what important risk with regard to the Prolift®? 9 the -- where the Gynemesh® PS mesh came from in terms 10 of what its use was before that, that mesh material? Q. Ultimately, where would you place it in the 10 11 A. I'm pretty sure that it was an existing hierarchy of your personal concern for patients with 11 12 hernia mesh, but I don't know for sure. Prolifts® in terms of the risks that you would fear Q. Is it based on basically what I just told the most or would least want to see with a patient? 13 13 14 you? 14 A. I haven't considered a hierarchy of all the 15 A. No. I think that's something I've heard 15 potential risks, so I know it's a significant risk 16 before. I can elaborate a little bit more. that I would be concerned about. When I was a fellow, towards the end of my Q. In some women who have Prolift® placed in 17 17 18 fellowship, we switched using meshes, and I think what their body and then develop dyspareunia as a result, 19 we switched to was ultimately what makes the mesh in the dyspareunia cannot be successfully treated, and it Prolift®. turns out to be a permanent condition that happens to 20 21 Q. Is there anywhere in this patient brochure 21 some women, correct? 22 where a patient is advised that one of the potential MR. SNELL: Objection, form. 22 risks of the Prolift® procedure is that the woman THE WITNESS: As with all surgical 23 could end up with dyspareunia? Is that spelled out, procedures in the vagina, that is a risk with and whether it's called dyspareunia or painful sexual Prolift®. Page 463 Page 465 1 relations or sexual intercourse? MR. SLATER: Move to strike. 2 BY MR. SLATER: A. So I'll go back to the risks and the terms. Q. Let's look on Page 10 under the heading "How 3 Sexual intercourse and dyspareunia are not words that does Gynecare Prolift® work?" Just read that to 4 I see here. 5 Let me look on the back under warnings and yourself and tell me if anywhere in there the patient 6 precautions. I do not see those words. 6 is told that part of what is going to happen is that Q. If you look at Page 10, there is a section 7 there's going to be an inflammatory response, there's that says "How is Gynecare Prolift® different from going to be a development of scar tissue and that is 8 other surgical alternatives?" part of the process of incorporating the Prolift® into 9 10 Do you see that section? 10 the woman's body? A. It states that the body tissues quickly grow 11 A. I do. 11 12 Q. The middle paragraph under that says, "It 12 into the pores of the mesh. Apart from that, it 13 allows for the restoration of sexual function by doesn't say the things that you said. 14 restoring normal vaginal anatomy." Q. The last sentence under "How does Gynecare Prolift® work" on Page 10 of the patient brochure 15 Do you see that? 16 A. I do. says, "Despite which of the defects you are 17 Q. Therefore, what Ethicon is telling patients experiencing, repair with Gynecare Prolift® will 18 is the Prolift® will restore your sexual function by correct these defects and restore normal support." 18 19 19 restoring your normal vaginal anatomy, if there are Do you see that? any issues with that, that's a positive piece of A. I do. 20 information to the patient, correct? Q. That sentence oversells to a patient 21 21 22 22 unrealistic expectations, correct? MR. SNELL: Objection, form. 23 Q. Nowhere in the brochure is there any -- is 23 24 the flip side explained, that one of the outcomes of 24 THE WITNESS: I think what it's 25 the Prolift® could be not restoration of sexual implying is that whether you have an anterior defect,

	Page 466	101		Dogo 169
	Page 466			Page 468
	a posterior defect or an apical defect, it can repair		it, because you can't say that to a patient, this will	
2	those different compartments.	2	correct your defects and restore your normal support?	
3	BY MR. SLATER:	3	You can just say that's the intention to expect to	
4	Q. The word you used is can, meaning it might	4	happen, it might, it could, it can, but you can't be	
	happen, but it doesn't always happen, right?	5	sure, right?	
6	A. Well, meaning that that particular part of	6	A. I think that's what this is implying, but,	
7	their prolapse can be addressed with this system.	7	again, I'm going to say the same thing over and over	
8	Q. Well, this sentence tells a patient	8	again, because it's a reference to despite which type	
9	rephrase.	9	of defect you have.	
10	The last sentence under "How does Gynecare	10	Q. Let's take a step back because let's take	
11	Prolift® work" tells a patient, "Despite which of the	11		
12	defects you are experiencing, repair with Gynecare	12	The last sentence under "How does Gynecare	
13	Prolift® will correct these defects and restore normal	13	Prolift® work" starts out to tell a patient, despite	
14	support."	14	which of the defects you are experiencing, that's the	
15	That's what it says, right?	15	first part, right?	
16	A. That's what it says.	16	A. Yes.	
17	Q. It's telling the patient if you have a	17	Q. That's communicating to the patient this can	
18	Prolift® used, your defects will be corrected and your	18	be used with poster, anterior or apex defects,	
19	normal support will be restored. It's saying that	19	correct?	
20	definitively that that is what will happen, correct?	20	A. Correct.	
21	That's what the words say on the page,	21	Q. We can agree that that's what that part of	
22	right?	22	· Ç	
23	A. And it's part of a sentence, and the first	23	A. Yes.	
24	part of the sentence is despite which of the defects	24	Q. Now, let's go to the next part of the	
25	you are experiencing.	25	sentence. The next part of the sentence tells you,	
-	Page 467			Page 469
	1 age 407			1 age 409
1		1	repair with Gynecare Prolift® will correct these	1 age 409
1 2	Q. Right. A. Right. So, again, it's referring to it's	1 2	repair with Gynecare Prolift® will correct these defects and restore normal support.	1 age 409
2	Q. Right.			1 age 409
2 3	Q. Right.A. Right. So, again, it's referring to it's	2	defects and restore normal support.	1 age 409
2 3 4	Q. Right.A. Right. So, again, it's referring to it's not it's a system that is not just limited to	2 3	defects and restore normal support. I want to ask you about the use of the word	1 age +09
2 3 4 5	Q. Right. A. Right. So, again, it's referring to it's not it's a system that is not just limited to fixing anterior compartment defects. It's not a	2 3 4	defects and restore normal support. I want to ask you about the use of the word will, okay?	1 age +09
2 3 4 5 6	Q. Right. A. Right. So, again, it's referring to it's not it's a system that is not just limited to fixing anterior compartment defects. It's not a system that's just limited, so, guess what, doc, I	2 3 4 5	defects and restore normal support. I want to ask you about the use of the word will, okay? A. Okay.	Tage +09
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2 3 4 5 6 7	Q. Right. A. Right. So, again, it's referring to it's not it's a system that is not just limited to fixing anterior compartment defects. It's not a system that's just limited, so, guess what, doc, I came in, I have a cystocele, this product, it only fix rectocele. So if that was the situation, Gynecare	2 3 4 5 6 7	defects and restore normal support. I want to ask you about the use of the word will, okay? A. Okay. Q. You would not tell a patient that the Prolift® will correct their defects and restore their	Tage +09
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Page 470 Page 472 1 100% of the women in correcting their defects and Q. One of the things Ethicon had to be very 2 sure of in this patient brochure was they didn't say 2 restoring normal support? A. I'm saying when it's placed, it does. Is 3 anything misleading to patients, right? 3 there a chance for recurrence later on? Absolutely. A. I think that a point of a patient brochure Q. So in order to make this sentence 5 is to give the patient information, not to mislead perfectly -- rephrase. 6 them. 6 So to make this sentence accurate, you would 7 Q. Look at Page 13 the section that says "Is Gynecare Prolift® right for me?" need to add something to the effect of, however, the defects can recur in the future, the support could Do you see that? 10 fail in the future, you could end up with a A. Yes. 10 11 recurrence? 11 Q. It states, in part, that the Prolift® is 12 A. If that was your intent in writing that 12 appropriate for almost all patients, including 13 sentence. 13 overweight patients, elderly patients and even those 14 Q. Well, to make it truthful and accurate in who have undergone previous operations for pelvic 15 providing information to a patient who is not a organ prolapse or stress incontinence. 16 doctor, you would need to say that to make this 16 Do you see that? accurate, correct? 17 18 A. Again --18 Q. Do you agree with that statement? 19 MR. SNELL: Object to form. Go ahead. 19 A. Yes. THE WITNESS: I'm going to give you the Q. There are certain patient groups that are 20 20 same answer I've given you three times before. 21 contraindicated per what's stated below, shouldn't be 21 If the intent of this sentence as you performed on pregnant women, infants or children or 22 22 23 were writing it as a member of Ethicon was to let 23 women who plan a future pregnancy, right? women know that your defects can be treated whether 24 A. They don't use the term contraindication, 25 anterior, posterior and apical, Prolift® can do that. but it does state that. Page 471 Page 473 1 I mean, I'll say that till I'm blue in the face. Q. Are there any other types of women that BY MR. SLATER: 2 should not have the Prolift® other than the little 3 list right there? Q. And you said can do it, right? A. That should not have it? A. Yes. Q. You didn't say will do it? Q. Yes. A. I said that is the intent, in my opinion, of A. No. Well, someone who doesn't have prolapse 7 this sentence. shouldn't have it. Q. So your testimony to this jury is it would Q. Should women -- should a woman who has a 8 9 be reasonable to expect a patient to read the word chronic pain condition have it, have a Prolift® put in 9 10 will and to in their own mind say, well, they just 10 her body? 11 mean can; is that what you're telling this jury? A. If she wants to have the surgery to correct 11 A. I'm not saying that. You said that. 12 12 her prolapse, that's certainly an option. 13 Q. Well, I'm asking you, is that what you're Q. Should a woman with a chronic pain condition 14 saying? be told that if she has the Prolift® put in her body 15 that she has an increased risk of suffering from pain A. No. Q. It's misleading to say that the Prolift® 16 afterwards? 16 17 will correct the defects and restore normal support 17 A. Increased compared to what? because we both know, and you would agree as an expert Q. Increased compared to women that doesn't 18 in this case, for some women, the defects are going to 19 have a chronic pain condition. A. I think that that's a reasonable thing that 20 recur and the support is going to fail, correct? 20 21 MR. SNELL: Object to form. Go ahead. someone should know, knowing what we've said up till 21 THE WITNESS: That is correct, but I 22 22 this point. 23 don't agree with your initial premise in that 23 Q. You think that would be reasonable to say, 24 sentence. 24 correct? 25 BY MR. SLATER: 25 A. Okay. I think that that would be a

	Confidential - Subject to Stipul		- Contraction	
	Page 474			Page 476
	reasonable thing to say. This was produced, I	1	Q. Am I correct that you reviewed very little	
2	believe, if we're talking about this, I think this was	2	by way of documents indicating what the people within	
3	produced before that conclusion that we've discussed	3	0 71	
4	earlier today was brought about.	4	point in time?	
5	Q. Once that information was available to	5	A. What I'm saying is I got stacks of documents	
6	Ethicon, that's information that would be reasonable	6	within the last two weeks that were about 2 feet high,	
7	to provide to patients, correct?	7	and I have only gotten through a small percentage of	
8	A. I don't think it would be necessary to put	8	that.	
9	on a patient brochure.	9	Q. As you sit here now, you don't feel that you	
10	Q. It would be necessary for Ethicon to put it	10	have a good understanding of what the people in	
11	someplace once Ethicon had that information so that	11	medical affairs at Ethicon thought with regard to mesh	
12	Ethicon could get that information out to doctors who	12	shrinkage, erosion or other topics?	
13	might not know about it and might not know to tell the	13	A. If you read my report, I don't think	
14	patient, right?	14	anywhere do I mention what the people in medical	
15	MR. SNELL: Objection to form. Go	15	affairs at Gynecare knew or didn't know.	
16	ahead.	16	Q. Let's turn to the page that at the top says	
17	THE WITNESS: We've already had this	17	"Clinical impact of mesh shrinkage."	
18	discussion. I already answered these questions. It	18	A. How far?	
19	was the opinion of one doctor that I'm aware of that	19	Q. It's about ten pages in or so.	
20	came to Ethicon and said that. Does that mean that	20	A. What's the topic the title again?	
21	Ethicon has to make that widely known to everybody? I	21	Q. "Clinical impact of mesh shrinkage."	
22	don't think so.	22	A. Not how to assess?	
23	BY MR. SLATER:	23	Q. It's right before that.	
24	Q. I'll show you a document marked as Exhibit	24	A. Right before that. I don't see anything	
25	1271 previously. I'm not going to go through the	25	before that. I see how to assess mesh shrinkage,	
	Page 475			Page 477
1	Page 475 whole thing, but I want to just go over a couple	1	clinical assessment.	Page 477
1 2			clinical assessment. Are you referring to something different?	Page 477
	whole thing, but I want to just go over a couple	1		Page 477
2 3	whole thing, but I want to just go over a couple things with you for a few moments. This is a	1 2	Are you referring to something different?	Page 477
2 3 4	whole thing, but I want to just go over a couple things with you for a few moments. This is a presentation titled "Mess Shrinkage: How to assess,	1 2 3	Are you referring to something different? Q. I'm definitely talking about something	Page 477
2 3 4	whole thing, but I want to just go over a couple things with you for a few moments. This is a presentation titled "Mess Shrinkage: How to assess, how to prevent, how to manage" authored by Velemir,	1 2 3 4	Are you referring to something different? Q. I'm definitely talking about something different, because I'm on a page that says this:	Page 477
2 3 4 5	whole thing, but I want to just go over a couple things with you for a few moments. This is a presentation titled "Mess Shrinkage: How to assess, how to prevent, how to manage" authored by Velemir, Fatton and Jacquetin.	1 2 3 4 5	Are you referring to something different? Q. I'm definitely talking about something different, because I'm on a page that says this: "Clinical impact of mesh shrinkage."	Page 477
2 3 4 5 6	whole thing, but I want to just go over a couple things with you for a few moments. This is a presentation titled "Mess Shrinkage: How to assess, how to prevent, how to manage" authored by Velemir, Fatton and Jacquetin. Do you see that?	1 2 3 4 5 6	Are you referring to something different? Q. I'm definitely talking about something different, because I'm on a page that says this: "Clinical impact of mesh shrinkage." A. Okay. Here I am. Got there.	Page 477
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	Confidencial - Subject to Scipul			
	Page 478		A 01	Page 480
	10.	1	A. Okay.	
2	Do you see that?	2	Q. Just so you know I'm not trying to give you	
3	A. I do.	3	a hard time.	
4	Q. Before you saw this document in preparing	4	A. Okay.	
5	for this deposition, were you aware of the fact that	5	MR. SLATER: Could you read the	
6	Professor Jacquetin and others in his group had	6	question back, please.	
7	reported a 19.6% symptomatic mesh shrinkage rate in a	7	(The court reporter read back the	
8	study done with the Prolift®?	8	record as requested.)	
9	A. I can't recall.	9	THE WITNESS: I think in some ways it	
10	Q. That's certainly a finding that is	10	was good; in some ways it was bad.	
11	concerning with regard to the complication and risk	11	BY MR. SLATER:	
12	profile with regard to the Prolift®, correct, that	12	Q. Let's look at some of the things that are	
13	almost 20% of the patients in this study had	13	described in this notification. Under "Summary of	
14	symptomatic mesh shrinkage?	14	Problem and Scope," the third paragraph which starts	
15	MR. SNELL: Objection, form.	15	with "in order to better understand."	
16	THE WITNESS: No. I think 20% of	16	Do you see where I am?	
17	patients who have surgery who have tenderness and	17	A. I do.	
18	pain, that's something whatever term you used	18	Q. Right in the middle of that paragraph	
19	significant or yes.	19	there's a sentence that reads, the review showed that	
20	BY MR. SLATER:	20	transvaginal pelvic organ prolapse repair with mesh	
	Q. Now we can finally talk about the things you		does not improve symptomatic results or quality of	
21	•	21		
22	prepped for.	22	life over traditional nonmesh repair.	
23	I've just handed you Exhibit 451.	23	Is that a conclusion that you agree with?	
24	You're familiar with that document, right?	24	A. No.	
25	A. I am.	25	Q. Let's go a little further down. The FDA	
	Page 479			Page 481
1				rage for
1	•	1	states, "In particular, the literature review revealed	ruge 101
	Q. This is the July 13, 2011 notification by	1		ruge tor
2	Q. This is the July 13, 2011 notification by the FDA with regard to mesh for pelvic organ prolapse,	1 2	that," and I'm going to start with the first bullet	1450 101
2 3	Q. This is the July 13, 2011 notification by the FDA with regard to mesh for pelvic organ prolapse, correct?	1	that," and I'm going to start with the first bullet point. Mesh used in transvaginal pelvic organ	Tage 101
2 3 4	Q. This is the July 13, 2011 notification by the FDA with regard to mesh for pelvic organ prolapse, correct? A. Transvaginal placement of mesh pelvic organ	1 2 3 4	that," and I'm going to start with the first bullet point. Mesh used in transvaginal pelvic organ prolapse repair introduces risks not present in	Tage 101
2 3 4 5	Q. This is the July 13, 2011 notification by the FDA with regard to mesh for pelvic organ prolapse, correct? A. Transvaginal placement of mesh pelvic organ prolapse, yes.	1 2 3 4 5	that," and I'm going to start with the first bullet point. Mesh used in transvaginal pelvic organ prolapse repair introduces risks not present in traditional nonmesh surgery for pelvic organ prolapse	Tage 101
2 3 4 5 6	Q. This is the July 13, 2011 notification by the FDA with regard to mesh for pelvic organ prolapse, correct? A. Transvaginal placement of mesh pelvic organ prolapse, yes. Q. And the FDA in this notification provided	1 2 3 4 5 6	that," and I'm going to start with the first bullet point. Mesh used in transvaginal pelvic organ prolapse repair introduces risks not present in traditional nonmesh surgery for pelvic organ prolapse repair.	Tage 101
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	Page 482			Page 484
1	Do you agree with that?	1	surgeries will not resolve the complications.	
2	A. No.	2	Do you agree with that statement?	
3	Q. Let's start with apical repair.	3	MR. SNELL: Objection, form. Which one	
4	Do you disagree with this sentence with	4	of them?	
5	regard to apical repair?	5	BY MR. SLATER:	
6	A. No.	6	Q. The two sentences that I just read.	
7	Q. You don't disagree?	7	A. Wait. Let me take them one at a time. Mesh	
8	A. I do not disagree.	8	erosion can require multiple surgeries to repair and	
9	Q. So you agree that there is no evidence that	9	can be debilitating for some women. Yes, I agree.	
10	transvaginal repair to support the top of the vagina,	10	Q. How about the next sentence?	
11	termed apical repair, with mesh provides any added	11	A. In some cases, even multiple surgeries will	
12	benefit compared to traditional surgery without mesh?	12	not resolve the complication. I think people have	
13	A. There is no evidence, and I think what they	13	probably reported that. That's not my experience.	
14	mean by this is evidence published in peer-reviewed	14	Q. Do you have an opinion one way or the other,	
15	journals, and I would agree with that.	15	based on whatever information is available to you	
16	Q. You believe there is evidence that	16	beyond your own experience, as to whether that's a	
17	transvaginal repair to support the back wall of the	17	true statement?	
18	vagina, termed posterior repair, with mesh provides	18	A. No.	
19	added benefit compared to traditional surgery without	19	Q. The sentence that says, mesh erosion can	
	mesh?	20	require multiple surgeries to repair and can be	
21	A. I do.	21	debilitating for some women, that statement is true of	
22	Q. You believe there's studies that document	22	the Prolift®, correct?	
	that?	23	A. I think the debilitating is a very	
24	A. I believe there's one study of recurrent	24	subjective term, but it certainly Prolift® can cause	
	prolapse that documents that.		mesh erosion, and there can be multiple surgeries	
25	prorapse that documents that.	25	mesh crosion, and there can be multiple surgeries	
	Page 483			Page 485
1	Page 483 Q. Which study?	1	required to repair it.	Page 485
1 2		1 2	required to repair it. Q. Based on information that's available to	Page 485
2	Q. Which study?		• •	Page 485
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2 3 4	Q. Which study?A. The Withagen, however you pronounce the name.	2	Q. Based on information that's available to you, not limited to your own experience, do you have	Page 485
2 3 4	Q. Which study?A. The Withagen, however you pronounce the name.Q. The RCT from 2010 or 2011, is that the study	2 3 4	Q. Based on information that's available to you, not limited to your own experience, do you have an opinion one way or the other as to whether when a	Page 485
2 3 4 5	Q. Which study?A. The Withagen, however you pronounce the name.Q. The RCT from 2010 or 2011, is that the study you're talking about?	2 3 4 5	Q. Based on information that's available to you, not limited to your own experience, do you have an opinion one way or the other as to whether when a woman has multiple surgeries to repair mesh erosion,	Page 485
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	Page 486			Page 488
1	A. There are certainly reports in the	1	mesh contraction may lead to an inability to engage in	
2	literature that associate that.	2	sexual intercourse?	
3	Q. Do you agree that with regard to the	3	A. No.	
4	Prolift®, that Prolift® mesh contraction is associated	4	Q. There's a excuse me.	
5	with vaginal shortening, vaginal tightening and	5	The last sentence on this page indicates	
6	vaginal pain in some women?	6	that "men may experience irritation and pain to the	
7	MR. SNELL: Objection, form.	7	penis during sexual intercourse when the mesh is	
8	THE WITNESS: Can you repeat the	8	exposed in mesh erosion."	
9	beginning part of the question.	9	That's a true statement, correct?	
10	MR. SLATER: Probably not. You can	10	A. Yes.	
11	read it.	11	Q. That's true of the Prolift®, correct?	
12	(The court reporter read back the	12	A. Correct.	
13	record as requested.)	13	Q. The various risks that we just went through	
14	THE WITNESS: No. Specifically vaginal	14	that you do agree apply to the Prolift®, do you think	
15	tightening.	15	that it is appropriate for those risks to be	
16	BY MR. SLATER:	16	communicated to a patient? Obviously, I'm talking	
17	Q. That's the part that you disagree with?	17	about when the Prolift® was available, that those	
18	A. That's the part that I disagree with.	18	risks should be communicated to a patient before they	
19	Q. You would agree that with regard to Prolift®	19	would be asked to consent to a Prolift® procedure?	
20	mesh contraction, that is associated in some women	20	MR. SNELL: Objection, form.	
21	with vaginal shortening and vaginal pain, correct?	21	THE WITNESS: I'm confused by your	
22	A. As I've testified many times today, I think	22	question. Are you talking about since this has come	
23	that what people refer to in the literature is	23	out or when the Prolift® first came on the market?	
24	contraction can cause pain.	24	BY MR. SLATER:	
25	Q. And can cause vaginal shortening?	25	Q. Well, let's talk about from the time this	
			,	
	Page 487			Page 489
				1 age 407
1	A. No, that's different.	1	came out.	1 age 40)
1 2		1 2	came out. A. Okay.	Tage 407
	A. No, that's different.			Tage 407
2	A. No, that's different.Q. In the last sentence on this page, the first	2	A. Okay.	1 age 407
2 3	A. No, that's different.Q. In the last sentence on this page, the first page of the July 2011 notification says, "both mesh	2	A. Okay.Q. With regard to those risks that you agreed	Tage 407
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2 3 4 5	A. No, that's different. Q. In the last sentence on this page, the first page of the July 2011 notification says, "both mesh erosion and mesh contraction may lead to severe pelvic pain." Let's stop there.	2 3 4 5	A. Okay. Q. With regard to those risks that you agreed apply to the Prolift®, those risks need to be communicated to a patient, correct?	rage 407
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			on and order of confidentiality
	Page 490		Page 49
	form?	1	MR. SLATER: You know what, that may
2	BY MR. SLATER:	2	be, but I'm taking this deposition on behalf of a lot
3	Q. The IFU and/or the patient brochure.	3	of people.
4	MR. SNELL: Objection, form.	4	MR. SNELL: I know. He's already
5	THE WITNESS: I think we've gone	5	testified what he thinks
6	through that multiple times already.	6	MR. SLATER: I didn't get an answer.
7	BY MR. SLATER:	7	MR. SNELL: should be in there or
8	Q. I've never asked you about this.	8	not.
9	A. Well, you're asking about the same	9	MR. SLATER: I just didn't get an
10	complications that we've already discussed. Is there	10	answer to the question.
11	something you're talking about that we haven't	11	MR. SNELL: You did get the answer you
12	discussed? Please point it out, if we have.	12	didn't want.
13	MR. SNELL: No, it's the same stuff.	13	MR. SLATER: No, I want an answer.
14	THE WITNESS: Just asking.	14	MR. SNELL: Object to the form.
15	BY MR. SLATER:	15	THE WITNESS: If we read it back, I
16	Q. I don't really know. I'm asking you a	16	think I said no.
17	question.	17	BY MR. SLATER:
18	A. I answered it.	18	Q. Well, is your answer to the question no?
19	Q. Well, you didn't, actually. You said	19	A. Yes.
20	basically I've answered it before, but let me ask you	20	Q. Okay.
21	this: Are there any risks on this FDA notification	21	A. I think I already said it.
22	that if Ethicon knew about those risks on the day the	22	(Discussion off the record.)
23	Prolift® was launched that they needed to have those	23	BY MR. SLATER:
24	risks included in the IFU?	24	Q. I'm going to hand you a document that was
25	A. No.	25	marked at a previous deposition as 1215.
	Page 491		Page 49
1	Q. Are there any risks listed on this FDA	1	This is an article that you authored,
2	notification from July 2011 that if Ethicon medical	2	·
3	affairs knew about them, that Ethicon should have	3	A. Correct.
4	warned about in the patient brochure?	4	Q. It refers to the Pelvic Surgeons Network,
5	A. I mean, we had this discussion at length.	-	right?
6	Q. It's a yes or no question.	6	A. It does.
7	A. Right, and if you're going to make me say	7	Q. The Pelvic Surgeons Network is what?
8	yes or no, I'm going to say no.	8	A. Network is a group of people that share a
9	Q. I'm not making you say anything. I'm just	9	common interest in pelvic reconstructive surgery.
10	asking you to answer the question.	10	Q. Who came up with the name Pelvic Surgeons
11	A. Well, you're not allowing me to explain	11	
12	myself or to say that I've already explained myself at	12	A. I don't recall.
13	length on this topic.	13	Q. Is there a formal organization known as the
14	Q. With all due respect, I haven't questioned	14	
15	you about the FDA notification, which is a discrete	15	A. It is not formal in the sense that we do not
16	document, okay.	16	have meetings. If you want to define formal, I'll be
17	MR. SNELL: But you're asking about all	17	happy to no, I don't think it's a formal
18	these things, contraction, erosion, pain, what needs	18	organization.
19	to be in there or not.	19	Q. You and some other people basically came up
20	MR. SLATER: Do you think these	20	with that name and then sent out the manuscript for
	questions are improper? I mean, what are we doing		this article to a bunch of doctors and asked them to
21		21	
22	here? We're wasting more time debating it. MR SNELL: No you're asking the same	22	sign something saying they agreed with the article,
23	MR. SNELL: No, you're asking the same	23	right?
2 4	quantion 100 times. That's what has twin - +		
24	question 100 times. That's what he's trying to say	24	A. We didn't ask them to sign it. We said
24 25	question 100 times. That's what he's trying to say and that's what I agree, I mean, so	24 25	A. We didn't ask them to sign it. We said we're presenting this, do you endorse it or not, and

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	Page 49			Page 496
	if you do, we consider you a member of the Pelvic	1	MR. SNELL: I'm sorry. Can you read	
	Surgeons Network.	2	that question back.	
3	Q. The Pelvic Surgeons Network, is that an	3	(The court reporter read back the	
4	organization where people pay dues, for example, to be	4	record as requested.)	
5	a member?	5	BY MR. SLATER:	
6	A. No.	6	Q. Let's go to the next page, the left column,	
7	Q. Do they have to apply to be a member?	7		
8	A. No.	8	statement that says, we agree that there is a relative	
9	Q. Is there a membership list of the Pelvic	9	paucity of comparative data regarding apical or apical	
10	Surgeons Network?	10	I'm going to start over.	
11	A. I'm not aware of one.	11	On Page 7 on the left column you state, "We	
12	Q. Let's look at some of the things you said.	12	agree that there is a relative paucity of comparative	
13	Look at the second page of this article.	13	data regarding apical and posterior support with TVM,	
14	You point out in the first column, "we	14	but we also feel that this issue is more complex than	
15	realize that many complications of TVM go unreported	15	this statement implies."	
16	to the MAUDE database."	16	You see that statement?	
17	You see that?	17	A. I do.	
18	A. I don't see it, but yes, I see it, yes.	18	Q. When you say there is a relative paucity of	
19	Q. There's no way, based on what's reported to	19	comparative data regarding apical and posterior	
20	the MAUDE database or any other data that you have	20	support with TVM, what do you mean?	
21	well, rephrase.	21	A. I am comparing it to when you look at data	
22	Do you have any opinion as to the extent to	22	of the anterior compartment.	
23	which there's underreporting of complications to the	23	Q. And you say that just below that a little	
24	MAUDE database? Do you have any opinion on	24	further down, "In regards to the posterior wall,	
25	quantifying that?	25	again, we acknowledge that there are less data	
	Page 49	5		Page 497
1	Page 49 MR SNELL: In this? Are you talking		available compared to the anterior wall "	Page 497
1 2	MR. SNELL: In this? Are you talking	1	available compared to the anterior wall."	Page 497
2	MR. SNELL: In this? Are you talking about in general? You just mean in general?	1 2	A. Correct.	Page 497
2 3	MR. SNELL: In this? Are you talking about in general? You just mean in general? MR. SLATER: I don't even know what	1 2 3	A. Correct.Q. Let's go to the next page.	Page 497
2 3 4	MR. SNELL: In this? Are you talking about in general? You just mean in general? MR. SLATER: I don't even know what that means.	1 2 3 4	A. Correct.Q. Let's go to the next page.A. Page 8.	Page 497
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	Confidencial - Subject to Scipula	101	
	Page 498		Page 50
1	mesh contraction. I certainly did not perform a	1	•
2	systematic review of that question.	2	You indicated that one of the outcomes that
3	Q. In the conclusion you say in part, "No one	3	you looked at was vaginal mesh contraction, correct?
4	is suggesting that mesh is recommended for all	4	A. Right.
5	patients."	5	Q. And you indicated decrease in total vaginal
6	What patients would you say should not get a	6	length greater than 3 centimeters occurred in 2.2% of
7	Prolift®? Is there any particular categories of	7	the patients?
8	patients?	8	A. That we had those numbers that we had pre
9	MR. SNELL: Objection, form.	9	and postoperative data on, yes.
10	THE WITNESS: People who don't have	10	Q. For some patients you didn't have the data,
11	pelvic organ prolapse.	11	correct?
12	BY MR. SLATER:	12	A. Correct.
13	Q. Was this article seen in any form before it	13	Q. And you have the indication that 17 out of
14	was published by anybody within Ethicon or any other	14	764 patients, so you had the data for 764 of the
15	medical device manufacturer?	15	patients?
16	A. Certainly not that I'm aware of.	16	A. Correct.
17	Q. Was it discussed, was the content discussed	17	Q. Do you consider a mesh contraction rate
18	by you or any of the co-authors, to your knowledge,	18	causing a decrease in total vaginal length of greater
19	with anybody at Ethicon or another medical device	19	than 3 centimeters of 2.2% of the patients, do you
20	manufacturer?	20	consider that to be high, low? Where would you put
21	A. Not that I recall.	21	that on a continuum?
			A. Well, first of all, I'd like to state that I
22	Q. With regard to the Prolift®, once the	22	
23	surgeon provides the information to the patient as to	23	am defining what I would consider a mesh contraction.
24	what's being recommended, what the options are, what	24	1 1
25	the potential risks and benefits are, ultimately, the	25	so I want to be clear about that.
	Page 499		Page 50
1	Page 499 decision about what treatment to have is the	1	Page 50 Q. As you define mesh contraction there, that
1 2		1 2	
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	Confidencial - Subject to Scipula		
	Page 502		Page 504
1	concern to me.	1	A. Repeat the question.
2	Q. Is a rate of 11.9%, from your perspective,	2	Q. Do you have any opinion one way or the other
3	high?	3	about whether there were patient rephrase.
4	A. I would say, from my perspective, given the	4	Do you have an opinion one way or the other
5	previous data that's been published on dyspareunia,	5	about whether there were surgeons who were performing
6	that's somewhere in the range of what people see.	6	Prolifts® who because of a lack of skill or experience
7	Q. When you say that an outcome percentage like	7	really should not have been doing the Prolift®?
8	this 11.9% is within the range of what people see,	8	A. Probably, yes.
9	just because that's in the range of what occurs	9	Q. Have you reviewed the professional education
10	doesn't necessarily make it something that should be	10	material that was utilized to train physicians with
11	accepted, right?	11	regard to the Prolift®, and I'm talking about the copy
12	A. When I'm saying that, I'm referring to	12	reviewed PowerPoints and other information promulgated
13	articles like the Lohman paper that looks at different	13	by Ethicon?
14	studies that looked at various ways of repairing	14	A. I certainly have some familiarity with them.
15	pelvic organ prolapse and what the outcomes are. So,	15	Q. What was the purpose of that material?
16	again, I don't mean to be argumentative, but when we	16	A. To provide professional education to
17	fix prolapse, there are not just one way to do it, and	17	physicians.
18	if you're fixing it, what you really want to be	18	Q. That was not meant to give a surgeon a
19	concerned about is if one procedure has a particular	19	particular skill level, correct? What I mean by that
20	higher rate of a negative outcome than another.	20	is the surgeon has their skill level as a surgeon.
21	So, again, I'm concerned if any patient has	21	The professional education was to give them specific
22	pelvic or dyspareunia, but it's a known risk of	22	training with regard to the Prolift®, correct?
23	repairing prolapse.	23	A. Correct.
24	Q. Your complication rates and success rates	24	Q. Did you do Prolift® training? Did you train
25	within your practice, do you believe that those rates,	25	surgeons on the Prolift® procedure?
	Page 503		Page 505
1	Page 503 as you're reporting, for example, in this PowerPoint,	1	Page 505 A. I did do some, yes.
1 2		1 2	
	as you're reporting, for example, in this PowerPoint,		A. I did do some, yes.
2 3	as you're reporting, for example, in this PowerPoint, are representative of what physicians in the general	2	A. I did do some, yes.Q. What type of training was that?A. I did a number of cadaver labs both on
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		il_	on and Order of Confidentiality
	Page 506		Page 508
1	A. I've heard that they were losing market	1	A. I see it.
2	share to other transvaginal mesh devices and that	2	Q. Have you reviewed that document?
3	given the medical-legal environment, they felt that it	3	A. I don't recall reviewing it.
4	was better to just stop producing it.	4	Q. Go to the next document Ethicon Report, PSE
5	Q. Any other reasons that you heard?	5	Accession No., et cetera, is that a document you
6	A. No, not that I can recall.	6	reviewed?
7	Q. Did you ever speak with anybody affiliated	7	A. I don't recall.
8	with Ethicon about that subject?	8	Q. Go to the third document, Ethicon March 5,
9	A. I spoke to my local sales representative.	9	2001 memo, et cetera, is that a document you reviewed?
10	Q. Who was that?	10	A. I don't remember reviewing that.
11	A. Christine President.	11	Q. The fourth document listed here, Ethicon
12	Q. Is she the person who told you what you just	12	December 2, 2001 memo to Maggie D'Aversa, et cetera,
13	related to me?	13	
14	A. No.	14	
15	Q. What did she tell you about why the Prolift®	15	· ·
16	was not being marketed any longer?	16	
17	A. She didn't know.	17	
18	Q. Did she speculate?	18	
	A. No, not that I recall.		
19			
20	Q. Are you aware that the indications for	20	•
21	Gynemesh® PS have been changed by Ethicon?	21	* *
22	A. I'm not aware of that.	22	
23	Q. There are blind passages as part of the	23	<u> </u>
24	Prolift® procedure, correct?	24	Q. Go to the next document listed, which is
25	A. Yes.	25	Ethicon Report PSE Accession No. 02-0579, Project No.
	Page 507		Page 509
1		1	
1 2	Q. Do you know what PVDF is?	1 2	48010, et cetera, did you review that document?
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	Confidencial - Subject to Scipula	_	_
	Page 510		Page 512
1	A. I can't recall anything.	1	A. I think so.
2	Q. Go to the next document, clinical study	2	Q. Do you know what it is? What is that
3	report evaluation of TVM technique for treatment of	3	document?
4	genital prolapse dated June 28, 2006, did you review	4	A. I think it's a computer-generated model for
5	that document?	5	the procedures and it's narrated.
6	A. I may have, but, again, I would give you the	6	Q. Is it something that you ever utilized or
7	same answer as the previous document.	7	saw in the course of your practice or professional
8	Q. Let's go to the next page. Ethicon Final	8	education?
9	Report PSE Accession No. 00-0035, an exploratory	9	A. I believe so.
10	91-day tissue reaction, et cetera, is that a document	10	Q. What use was made of that document; do you
11	you reviewed?	11	know?
12	A. I may have. Again, I remember reviewing	12	A. It's helpful in getting a three-dimensional
13	some documents regarding animal models.	13	appreciation of pelvic floor anatomy.
14	Q. Is there anything about this document that	14	Q. Does that animation, from your prospective,
15	you can tell me now?	15	provide a fair representation of, in broad
16	A. No.	16	illustrative terms, the Prolift® procedure?
17	Q. Anything of any significance?	17	A. If I'm recalling the proper thing, yes, it
18	A. No, not at this moment.	18	does.
19	Q. The next document, Final Report PSE Study,	19	Q. The next document listed, Gynecare Prolift®
20	No. 08-0311; Project No. 67624, some sort of a rabbit	20	Pelvic Floor Repair Systems Procedure DVD, do you know
21	study, is that something that you read?	21	specifically which procedure DVD that is?
22	A. Same answer as last question.	22	A. I couldn't say for sure.
23	Q. The next document, chart comparing Ethicon,	23	Q. Did you review it?
24	AMS and Bard's products by characteristic, area	24	A. I've reviewed a procedure DVD of one of the
25	weight, largest pore size, et cetera, is that a		French surgeons doing the Prolift®.
	8,8		
	Page 511		Page 513
1	Page 511 document you reviewed?	1	Page 513 Q. Do you know if that's what this is?
1 2		1 2	
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2 3	document you reviewed? A. I don't recall.	2 3	Q. Do you know if that's what this is?A. I couldn't say for sure, don't recall.
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	Confidential - Subject to S	Page 514	LIC	Page 516
1	Jones from Celia M. Witten with FDA dated 1/8/02	1 age 314	1	review that document?
2	regarding Gynemesh® Prolene® synthetic surgical mesh,		2	A. I don't recall.
3			3	Q. If you skip down a few lines it says, 2007
4	Is that a document you reviewed?		4	and 2008 Gynecare Prolift® Pelvic Floor Repair Systems
5	A. I don't recall reviewing it.			- slides (46 pages). What is that?
6	Q. The next document, memo to materials to		6	A. I believe that is a PowerPoint presentation
7				regarding professional education.
8	Gynecare Worldwide Ethicon dated October 10, 2002		8	Q. Did you review it in connection with this
9	regarding Gynemesh® PS, is that a document you		9	case?
10	reviewed?		10	A. Yes, I did.
11	A. I don't recall reviewing it.		11	Q. Is it of any significance to you on any
12	Q. The next document, memo to customer from		12	particular issue?
13	Sean M. O'Bryan dated February 8, 2005 regarding		13	A. If you wanted to name an issue, I could say
14	Gynecare Prolift®, did you review that document?		14	whether it's significant or not. I think yes, I
15	A. I don't recall reviewing that document.		15	mean, yeah, it certainly goes to what professional
16	Q. If you could just turn back three pages to		16	education Gynecare provided to physicians.
17	the beginning where it says "Other Documents." This		17	Q. Next it says 2005 to 2006, Gynecare Prolift®
18	is, again, in your additional materials section of		18	Pelvic Floor Repair Systems - slides (16 pages). Do
19	your original report where it says Other Documents.		19	you know what that is?
20	At the very bottom of the page it says Clinical Expert		20	A. I think that's a similar slide set for
21	Report Gynecare Prolift® Pelvic Floor Repair System		21	professional education that I believe I reviewed.
22	dated July 2, 2010, did you review that document?		22	Q. The next item, Gynecare Gynemesh® PS
23	A. I may have. I don't recall.		23	nonabsorbable Prolene® Soft mesh IFU, did you review
24	Q. Go to the next page. At the top, clinical		24	that?
25	study report evaluation of the TVM technique for		25	A. I think I probably did.
		Page 515		Page 517
1	treatment of genital prolapse, is that something you		1	Q. Do you have any recollection of reading it?
2			2	A. I can't recall right now.
3	A. I may have, but I don't recall. I couldn't		3	Q. Is there anything that you can point to now
4	tell you anything substantive about it.		4	that's of significance to you with regard to that
5	Q. The next document, would the answer be the		5	document?
6	same?		6	A. I can't recall right now.
7	A. Yes.		7	MR. SLATER: Thank you. I don't have
8	Q. Now, the third document on this page, would		8	any other questions for you tonight.
9	the answer be the same?		9	THE WITNESS: Thank you.
10	A. Yes.		10	MR. SLATER: I am going to reserve my
11	Q. The fourth document, which says Exhibit 15,		11	rights only with regard to some e-mails I had
12	letter to Bryan Lisa from Mark Melkerson, is that a		12	exchanged with defense counsel the last couple days,
13	document you reviewed?		13	not with counsel who is present. We had asked for
14	A. I don't recall.		14	documents to be searched to see if there was anything
1 -				
15	Q. The next document, memo to Jennifer Paine		15	in the files of Ethicon with regard to Dr. Murphy,
	Q. The next document, memo to Jennifer Paine from Renee Selman dated 1/16/08, did you review that		15 16	in the files of Ethicon with regard to Dr. Murphy, other than what we have been previously produced in
16				
16 17	from Renee Selman dated 1/16/08, did you review that		16	other than what we have been previously produced in
16 17	from Renee Selman dated 1/16/08, did you review that document?		16 17	other than what we have been previously produced in the DFSes, and counsel never apparently did the search
16 17 18 19	from Renee Selman dated 1/16/08, did you review that document? A. I don't recall reviewing that document.		16 17 18	other than what we have been previously produced in the DFSes, and counsel never apparently did the search or produced any documents. So in case something were
16 17 18 19 20	from Renee Selman dated 1/16/08, did you review that document? A. I don't recall reviewing that document. Q. Next document, one year objective and		16 17 18 19	other than what we have been previously produced in the DFSes, and counsel never apparently did the search or produced any documents. So in case something were to come out that we thought was really pressing, we'll
16 17 18	from Renee Selman dated 1/16/08, did you review that document? A. I don't recall reviewing that document. Q. Next document, one year objective and functional outcomes well, I know you saw that.		16 17 18 19 20	other than what we have been previously produced in the DFSes, and counsel never apparently did the search or produced any documents. So in case something were to come out that we thought was really pressing, we'll reserve our rights; otherwise, thank you very much.
16 17 18 19 20 21	from Renee Selman dated 1/16/08, did you review that document? A. I don't recall reviewing that document. Q. Next document, one year objective and functional outcomes well, I know you saw that. That's no problem.		16 17 18 19 20 21	other than what we have been previously produced in the DFSes, and counsel never apparently did the search or produced any documents. So in case something were to come out that we thought was really pressing, we'll reserve our rights; otherwise, thank you very much. THE WITNESS: Thank you.
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1 1	Page 518	1	Page 520
	finally have a real lawyer sitting next to you.		Prolift®.
2	THE WITNESS: Not particularly.	2	Can you turn to page 21 of your report.
3	MR. SLATER: If I was defending this	3	Did the Fatton 2007 study concern the
4	deposition, it would have taken 45 minutes.	4	Prolift® system or the TVM?
5	THE WITNESS: I doubt that.	5	A. The Prolift® system.
6	BY MR. SNELL:	6	Q. Turn, if you would, to Page 20 of your
7	Q. You got your report there, there's a couple		report.
8	things.	8	A. Page 20?
9	Dr. Murphy, my name is Burt Snell. I	9	Q. Yes. You were asked questions about whether
10	represent Ethicon and Johnson & Johnson. We know each	10	the pore size of a mesh needed to be 1 millimeter.
11	other. I just want to ask you a few follow-up	11	Do you recall those questions, in general?
12	questions in response to plaintiffs' counsel's	12	MR. SLATER: Objection. You can
13	questions.	13	answer.
14	The first is concerning the TVM study. The	14	THE WITNESS: I do.
15	plaintiffs' counsel asked you some questions about	15	MR. SLATER: What page are you on?
16	that study, correct?	16	MR. SNELL: Twenty.
17	A. Correct.	17	BY MR. SNELL:
18	Q. And I believe he asked you whether you	18	Q. Page 20, do you set forth at the bottom of
19	recalled if the TVM study was funded by Ethicon?	19	your report the definition of macroporous?
20	A. Yes.	20	MR. SLATER: Objection. You can
21	Q. Do you know whether the US study strike	21	answer.
22	that.	22	THE WITNESS: Yes.
23	Do you know whether the US TVM study was	23	BY MR. SNELL:
24	funded in part by Ethicon?	24	Q. And what is that?
25	A. Yes, it was.	25	A. Greater than 75 microns.
	P. 510		D 521
1	Page 519 Q. Your report Pages 17 to 19, do you discuss	1	Page 521 Q. Plaintiffs' counsel moved to strike quite a
	the TVM studies in your report?	2	few of your answers. I want to give you an
3	A. I do.	3	opportunity to give what you believe are accurate and
4	Q. And I believe you were asked questions about		opportunity to give what you believe are accurate and
	Q. That believe you were ushed questions about	1 4	complete answers
1 5	whether the upper confidence interval bound in the	4	complete answers. MR_SLATER: Objection
١.	whether the upper confidence interval bound in the French study was more than 20% and thus not meeting	5	MR. SLATER: Objection.
6	French study was more than 20% and thus not meeting	5 6	MR. SLATER: Objection. BY MR. SNELL:
6 7	French study was more than 20% and thus not meeting the primary endpoint.	5 6 7	MR. SLATER: Objection. BY MR. SNELL: Q. Setting aside the potential for mesh
6 7 8	French study was more than 20% and thus not meeting the primary endpoint. Do you recall that question or questions	5 6 7 8	MR. SLATER: Objection. BY MR. SNELL: Q. Setting aside the potential for mesh contraction and mesh erosion, do other pelvic organ
6 7 8 9	French study was more than 20% and thus not meeting the primary endpoint. Do you recall that question or questions concerning whether the French study met the primary	5 6 7 8 9	MR. SLATER: Objection. BY MR. SNELL: Q. Setting aside the potential for mesh contraction and mesh erosion, do other pelvic organ prolapse surgeries have the same type of risk as the
6 7 8 9	French study was more than 20% and thus not meeting the primary endpoint. Do you recall that question or questions concerning whether the French study met the primary endpoint?	5 6 7 8 9	MR. SLATER: Objection. BY MR. SNELL: Q. Setting aside the potential for mesh contraction and mesh erosion, do other pelvic organ prolapse surgeries have the same type of risk as the Prolift®?
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	Page 52			Page 524
1	Do you recall those questions?	1	MR. SLATER: Objection. You can	
2	A. I recall some of them, yes.	2		
3	Q. Can chronic pain patients have a potential	3	THE WITNESS: Yes.	
4	increased risk with any pelvic organ prolapse surgery?	4	BY MR. SNELL:	
5	A. Yes.	5	Q. And I believe your testimony was that anyone	
6	Q. Is the relationship between chronic pain	6	with a brain would know mesh exposure is a potential	
7	patients and surgery specific to the Prolift®?	7	risk when using mesh?	
8	MR. SLATER: Objection. You can	8	MR. SLATER: Objection.	
9	answer.	9	THE WITNESS: Yes, I think that was my	
10	THE WITNESS: No, not that I'm aware	10	testimony.	
11	of.	11	BY MR. SNELL:	
12	BY MR. SNELL:	12	Q. By 2005 had mesh been used to treat prolapse	
13	Q. If you have the exhibits, let's turn back	13	for decades?	
14	to going to go in pretty much reverse order, turn	14	A. Yes.	
15	back to Plaintiffs' Exhibit 895, which were the	15	MR. SLATER: Objection. You can	
16	Short-Term Results of the Prolift® Procedure in 349	16	v	
	Patients.	17	THE WITNESS: Yes, it had.	
18	A. Get there in just one minute. Got it, I	18	BY MR. SNELL:	
19	think. Is this 895, is that what you're referring to?	19	Q. Was mesh exposure reported in the literature	
20	Q. Yes.	20	before 2005?	
21	A. Yes.	21	MR. SLATER: Objection. You can	
22	Q. Turn, if you would, to the Results section,	22	answer.	
	Bates Number 2689.			
23		23	THE WITNESS: Yes, it was.	
24	A. Results section where, 2689, yes, I'm there.		BY MR. SNELL:	
25	Q. And third paragraph that begins	25	Q. Turn, if you would, to Exhibit 1216, the	
	Page 52	3		Page 525
1	"post-operative findings included," are you there?	1	"One-year anatomic and quality of life outcomes after	
2	A. Yes.	2	the Prolift® procedure" published in 2008.	
3	Q. Plaintiffs' counsel asked you a question	3	A. I have it here.	
4	about the sentence that says the majority (73%) of	4	Q. Plaintiffs' counsel asked you about the	
5	dyspareunia symptoms resolved by 3 or 6 month	5	change in vaginal length in this study. Turn, if you	
6	follow-up visit, and then he asked you about this 1.7%	6	would, to the third page, e3. In the middle column it	
7	of patients who experienced persistent discomfort.	7	reports that the average change of vaginal length was	
8	Do you recall those questions?	8	negative 0.6 centimeters, plus or minus 1.1.	
9	A. Yes.	9	Do you see that?	
10	Q. Now, that was persistent discomfort at six	10	A. On e3?	
	months, correct?	11	Q. Yeah, right in the middle column.	
12	A. Correct.	12	A. Oh, I'm sorry. I was looking at the table.	
13	Q. And patients can get better from six months,		Yes.	
14	if you look at them again a year or more than that	14	Q. Was that believed to be clinically	
15	down the road?	15		
16	MR. SLATER: Objection.	16	A. It was not.	
17	THE WITNESS: Yes, they can.	17	Q. And on e5 in the top left-hand corner, do	
18	BY MR. SNELL:	18	you talk about the different techniques that were used	
19	Q. Let's go to Exhibit 1217, which is "Vaginal	19	that you believe led to a low mesh exposure rate?	
20	Hysterectomy at the Time of Transvaginal Mesh	20	MR. SLATER: Objection, you can answer.	
21	Placement."	21		
		100	Q. Strike that.	
22	A. Yes, I have it.	22		
22 23	Q. Plaintiffs' counsel asked you questions	23	Do you talk about the techniques used to	
	Q. Plaintiffs' counsel asked you questions about mesh exposure in this study.	23 24	Do you talk about the techniques used to prevent measure erosion after transvaginal placement?	
23	Q. Plaintiffs' counsel asked you questions	23	Do you talk about the techniques used to	

	Confidential - Subject to		. C		
		Page 526			Page 528
1	answer.		1	Q. Do you remember plaintiffs' counsel asking	
2	THE WITNESS: We're looking at the		2	you about that?	
3	third column?		3	A. I do.	
4	BY MR. SNELL:		4	Q. A little further down with regard to that	
5	Q. I'm sorry if I said the third column. On		5	trial, it states that they also failed to meet their	
6	Page e5 on the first column, do you discuss techniques		6	desired sample size based on prospective power	
7	used to prevent mesh erosion after transvaginal		7	calculation?	
8	placement?		8	A. Yes.	
9	A. I do.		9	Q. And that was for the Weber study?	
10	Q. Plaintiff's Exhibit 240, the transcript from		10	A. Correct.	
11	Dr. Lucente's webinar.		11	Q. On the last page with regard to the	
12	A. I have it.		12	recommendations, plaintiffs' counsel asked you	
13	Q. Do you see the date on this is		13	questions about those recommendations, correct?	
14	December 14th, 2008?		14	A. Yes.	
15	A. At the top I see December 15th, 2008. I		15	Q. And was the risk of erosion identified as	
16	think the time is 14:59, yeah, if I'm looking at the		16	the known unique risk associated with the use of	
17	same place you're looking.		17	grafts?	
18	Q. With regard to chronic pain patients in		18	A. Yes.	
19	Dr. Lucente's opinions regarding them, have you seen		19	Q. The potential risks include chronic pain and	
20	those opinions set forth in a journal available to		20	dyspareunia. Are those potential risks with all	
21	pelvic floor surgeons?		21	prolapse surgeries?	
22	A. Yes, I have.		22	MR. SLATER: Objection. You can	
23	Q. Turn, if you would, to the clinical turn,		23	answer.	
24			24	THE WITNESS: Yes.	
	guidelines on vaginal graft use from 2008.		25	BY MR. SNELL:	
	8				
		Page 527			Page 529
1	A. I have it.	Page 527	1	Q. Plaintiffs' counsel asked you about topics	Page 529
1 2	A. I have it.Q. Did these clinical practice guidelines focus	Page 527	1 2	Q. Plaintiffs' counsel asked you about topics such as trimming the mesh and dealing with	Page 529
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2	Q. Did these clinical practice guidelines focus	Page 527	2	such as trimming the mesh and dealing with	Page 529
2 3	Q. Did these clinical practice guidelines focus on whether there were randomized, controlled trials	Page 527	2	such as trimming the mesh and dealing with complications.	Page 529
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1 BY MR. SNELL: 2 Q. And when you actually led cadaver labs, is a that something you taught to physicians? 4 A. Yes. 5 MR. SLATER: Objection. You can 6 answer. I realize it as after but went too quick for 7 me. 7 me. 9 Q. If surgeons encountered a complication and 10 wanted to seek input from someone such as youned (a 1) precept or a protect, were they available to do such? 12 A. Absolutely. 13 Q. Paintiffs counsel asked you some questions 13 metal by Velection of the IFU. 14 about the IFU and the specific — in certain specific 15 for protect that it is a few to the IFU. It 15 protect of a proceed that a few to the IFU. It 16 protect of a protect that it is a few to the IFU. It 17 protect of the IFU. It 18 protect of a protect that it is a few to the IFU. It 19 states, training on the use of Gyaccare Prolitics 19 poyou see that? 10 poyou see that? 11 Q. And it also referenced the recommended and a twaitable. 12 A. Yes. 13 Q. And who are we? 14 Q. And it also referenced the recommended and a twaitable. 15 Section of the IFU. It 18 protection of the IFU is 19 states, training on the use of Gyaccare Prolitics 19 poyou see that? 10 poyou see that? 11 Q. And it also referenced the recommended and a twaitable. 12 A. Yes. 14 Q. And it also referenced the recommended and a twaitable. 15 Q. Lock at the very front of the IFU is 18 protection in the IFU is 19 pro	1	Confidential - Subject to Stipt Page 5			Page 532
2 Q. And when you actually led cadaver labs, is 3 that something you taught to physicians? 4 A. Yes. 4 RS. SATER: Objection. You can 6 mRS. SLATER: Objection. You can 7 me. 7 me. 7 me. 8 BY MR. SNFLL: 8 Q. It suggests encountered a complication and 10 wanted to seek input from someone such as yourself, a 11 precept or a proctor, were they available to do such? 12 A. Absolutely. 13 Q. Palaintiff's consuel asked you some questions 14 About the Ell-L 15 Do you recall that? 15 A. Yes. I quoted that Abed study that looked 15 sections of the IFU. 16 Do you recall that? 17 A. Yes. 18 Q. Look at the very front of the IFU. It 19 states, training on the use of Gynecare Prolife® 20 Petivic Floor Repair Systems is recommended and 21 available. 22 Do you see that? 23 A. How far down are we? 24 Q. On the very first page, the third line. 25 A. Yes. 26 Q. Bit BITU intended for surgeons like 27 yourself 28 A. Yes. 29 Page 531 20 A. And it also referenced the recommended 21 surgical technique guide right below that? 21 A. Yes. 21 Turn to Fage 330 and 331. You talk about 1 23 devandors was promounted and requestions. 24 A. States, training on the use of Gynecare Prolife® 25 often developed by surgeons? 26 A. Turn to Edubii Number 5, Vaginal Prolapse 27 Q. It was to Edubii Number 5, Vaginal Prolapse 28 Repair, Sware Repair Versus Wish Augmentation: A 29 Urogyaccology Perspeciev.* 3 A. There was a surgical intervention? 4 Q. Nes the article from 2012. 4 A. Turn to Fage 330 and 331. You talk about 1 3 A. State article from 2012. 5 THE WTINESS: Yes. 5 Page 531 5 Q. Day and an object from the prolapse of the pr	1			MR SLATER: Objection	1 uge 332
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4 A. Yes. MR. SLATER: Objection. You can 5 answer. I realize it's after but went too quick for 7 mc. 8 RY MR. SNELL: 8 RY MR. SNELL: 8 RY MR. SNELL: 9 Q. If surgeous encountered a complication und 10 wanted to seek input from someone such as yourself, a 11 precept or a protocor, were they available to do such? 12 A. Absolutely. 13 Q. Plaintiff's counsel asked you some questions a drout the Eff and the specific—in certain specific 15 sections of the IFU. 16 Do you recall that? 17 A. Yes. 18 Q. In the way of the IFU. 19 Do you recall that? 19 A. Yes. 10 J. Look at the very froat of the IFU. It 20 Look at the very froat of the IFU. It 21 Do you seen that? 22 Do you seen that? 23 A. How far down are we? 24 Q. On the very first page, the third line. 25 Do you see that? 26 Q. Natl it also referenced the recommended and auraliable. 27 A. Yes. 28 Q. Natl it also referenced the recommended and auraliable. 29 Do you see that? 20 Q. Was the transvaginal mush procedure also Questions? 21 A. Yes. 22 Do you see that? 23 A. Yes. 24 Q. On the very first page, the third line. 25 Do you see that? 26 Q. Is the IFU intended for surgeons like 27 Q. Is the IFU intended for surgeons like 28 Repair, Summe Repair Versus Meth Augmentation: A 29 Urgspracology Perspective. 30 A. I think so, yes. 4 Q. Is the IFU intended for surgeons like 5 Urgspracology Perspective. 5 Urgspracology Perspective. 6 A. I think so, yes. 6 A. I think so, yes. 7 Q. Turn to Eshibit Number 5, "Vaginal Prolapse 8 Repair, Summe Repair Versus Meth Augmentation: A 9 Urgspracology Perspective. 19 YMR, SNELL: 19 WMR, SNELL: 19 WMR, SNELL: 19 THE WITNESS: Yes. 20 Q. Do and so discuss how patients can 21 Q. He asked you to read the top part of "Is 22 Do you also discuss how patients can 23 Q. And are also set treatment modellities also 24 Q. On the very first page, the third line. 25 Grynear Prolifit® right for me? 26 Grynear Prolifit® right for me? 27 Do you are all that about the different thempies? 28 Q. Do you also discuss how patients can 29 Grynear Prolifit® right		, ,			
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6 answer. I realize it's after but went too quick for 7 ne. 8 BY MR. SNELL: 9 Q. If surgeons encountered a complication and 10 warned to seek input from someone such as yourself, a 11 precept or a protein, were they available to do such? 12 A. Absolutely, 13 Q. Paintiffs' counsel asked you some questions 14 about the IFU and the specific — in certain specific 15 sections of the IFU. 16 Do you recall that? 17 A. Yes. 18 Q. Look at the very froat of the IFU. It 19 States, training on the use of Gynecare Prolift® 19 plainiffs' counsel asked you some questions 10 power time with regard to native tissue repairs. 20 Pelvis floor Repair Systems is recommended and 21 available. 22 Du you see that? 23 A. How far down are we? 24 Q. On the very first page, the third line. 25 A. Yes. 26 Q. And it also referenced the recommended 28 surgical technique guide right below that? 29 A. Yes. 20 Q. Was the farmy intended for surgeons like 29 you seen that? 20 Q. Is the IFU intended for surgeons like 29 A. Yes. 20 Q. Turn to Eshibit Number 5, "Vaginal Prolapse 20 Repears, Surure Repair Versus Mesh Augmentation: A 21 Q. Is the article from 2012. 22 Turn to Page 33 and 31, You talk about 23 developed perspective. 24 Q. Is the traits injury to the blood vessels of the pelvis, 25 MR. SLATER: Objection. 26 Play MR. SNELL: 27 THE WITNESS: Yes. 28 Play MR. SNELL: 28 BY MR. SNELL: 39 With SNELL: 30 Op our aceal that a develop 31 BY MR. SNELL: 31 BY MR. SNELL: 32 Q. Was seen other groups who had a zero percent exposure 32 Q. Flaintiffs counsel asked you to some questions 31 the range was from zero and up. 31 do not the west of the IFU. It 32 BY MR. SNELL: 31 BY MR. SNELL: 32 Du you aceal that? 32 Du you aceal that? 33 developed by surgeons? 44 Q. Is the training on the use of Gynecare Prolifts 45 Durchard for surgeons like 46 Q. It with the patient brochure, the initial patient 47 Durchard for surgeons like 49 Under what are the risks, where it 40 Under what are the risks, where it 51 demifies injury to the blood vessels of the pelvis, 52 de					
7 BY MR. SNELL: 8 BY MR. SNELL: 9 Q. If surgeons encountered a complication and 10 wanted to seek input from someone such as yourself, a 11 precept or a princine, were they available to do such? 12 A. Aboulously. 13 Q. Plaintiffs' counsel asked you some questions 14 about the FU and the specific — in certain specific 15 Sections of the FU. 16 Do you recall that? 17 A. Yes. 18 Q. Look at the very front of the IFU. It 18 Q. Look at the very front of the IFU. It 19 States, training on the use of Gynecare Prolifi® 20 Pelvic Floor Repair Systems is recommended and available. 21 A. How far down are we? 22 Do you see that? 23 A. How far down are we? 24 Q. On the very first page, the third line. 25 A. Yes. 26 Q. Is a first from any expection. 27 A. Yes. 28 Yes. 29 Do you See that? 29 Do you see that? 20 Do you see that? 21 A. Yes. 22 Do you see that? 23 A. How far down are we? 24 Q. On the very first page, the third line. 25 A. Yes. 26 Q. That to Exhibit Number 5, 'Vaginal Prolapse Surgical technique guide right hellow that? 26 A. Yes. 27 Q. Turn to Exhibit Number 5, 'Vaginal Prolapse 28 Repairs, Suruse Repair Yersus Mesh Augmentation: A 29 Urogynecology Perspective. 3 A. Yes. 4 Q. On the very first page, the surgical through the parties the patient brochure, the initial parient 3 A. Yes. 4 Q. On the very first page, the surgical through the patient brochure, the initial parient 4 Under what are the risks, where it 5 dentifies injury to the Blood vessels of the pelvis, 6 nerve damage, difficulty urinating, bladder and bowel 7 injury and a risk of the mesh material becoming 8 Repairs, Suruse Repair Versus Mesh Augmentation: A 8 Urogynecology Perspective. 9 that reading that could scare a patient? 10 A. I have it here. 11 MR. SLATER: Objection. 11 answer. 12 THE WITNESS: Yes. 13 WR. SNELL: 14 Q. Do you also discuss how patients can 15 Swight to strike earlier, correct? 16 MR. SLATER: Objection. 17 He WITNESS: Yes. 18 W. MR. SNELL: 19 Q. He asked you to read the top part of "Is 20 Q. And are those treatment modalities als		·		·	
8 BY MR. SNELL: 9 Q. If surgeons encountered a complication and 9 you seen other groups who bad a zero percent exposure 10 rate? 11 A. Yes, I quoted that Abed study that looked 12 A. Absolutely. 12 A. Absolutely. 13 decrease from zero and up. 14 about the IFU and the specific – in certain specific 15 sections of the IFU. 16 Do you recall that? 17 A. Yes. 18 Q. Turn to Exhibit Number 7, the transvaginal 19 states, training on the use of Gynecare Prolifi® 10 states, Training on the use of Gynecare Prolifi® 11 about the West of the States of Gynecare Prolifi® 12 available. 13 A. Yes. 14 Q. Turn to Exhibit Number 7, the transvaginal 15 mesh ultrascound study by Veleniir. You know what, 16 forget that. 17 Plaintiffs' counsel asked you some questions 18 about how surgical procedures for prolapse developed 19 over time with regard to native tissue repairs. 10 Do you recall have great the tissue repairs. 11 Q. On the very first page, the third line. 22 Do you see that? 23 A. Yes. 24 Q. On the very first page, the third line. 25 A. Yes. 26 Q. And it also referenced the recommended 27 surgical technique guide right below that? 28 Q. Is the IFU intended for surgeons like 29 your first page, the third line. 29 Q. Turn to Exhibit Number 5, 'Vaginal Prolapse 20 Repair, Suture Repair Versus Mesh Augmentation: A 21 G. A. I have it here. 22 G. Was the transvaginal mesh procedure also 23 other questions. 4 Under what are the risks, where it 24 d. A. I have it here. 25 d. A. I have it here. 26 G. D. It is the article from 2012. 27 Turn to Exhibit Number 5, 'Vaginal Prolapse 28 Repair, Suture Repair Versus Mesh Augmentation: A 29 Uregyrencology Perspective. 20 Q. Was called a surgical microention? 21 MR. SLATER: Objection. 22 Turn to Page 330 and 331. You talk about 23 G. D. You also discuss how patients can 24 Q. Dea sked you so recall have about the different therapies? 25 Q. Do you also discuss how patients can 26 Gynecare Prolifi® right for me?" 27 Do you recall that about t		•		·	
9 Q. If surgeons encountered a complication and 10 wanted to seek input from someone such as yourself, a 11 precept or a proctor, were they available to do such? 12 A. Absolutely. 13 Q. Plaintiffs counsel asked you some questions 14 about the PLU and the specific — in certain specific 15 sections of the IFU. 16 Do you recall that? 17 A. Yes. 18 Q. Look at the very front of the IFU. It 19 states, training on the use of Gynecare Prolifi® 20 Pelvire Floor Repair Systems is recommended and 21 available. 22 Do you see that? 23 A. How far down are we? 24 Q. On the very first page, the third line. 25 A. Yes. 26 Q. Is the IFU intended for surgeons like 27 Q. And it also referenced the recommended 28 surgical technique guide right below that? 29 yourseled spair Systems which was a couple 20 A. I share it here. 21 Q. Is the IFU intended for surgeons like 22 yoursele spair Systems which was a surgical recording. 23 A. How far down are we? 24 Q. On the very first page, the third line. 25 A. Yes. 26 Q. Is the IFU intended for surgeons like 36 A. Yes. 37 Q. Is the IFU intended for surgeons like 39 yoursele share it here. 40 Q. Turn to Exhibit Number 5, "Vaginal Prolapse 41 Repair Suture Repair Versus Mesh Augmentation: A 41 Urogenecology Perspective." 41 Q. Turn to Page 330 and 331. You talk about 42 Urogenecology Perspective." 43 A. I have it here. 44 Q. Da the article from 2012. 45 Turn to Page 330 and 331. You talk about 46 Septime with equive to the other experiments of the article from 2012. 46 White Shart Repair Versus Mesh Augmentation: A 47 Grant of Exhibit Number 5, "Vaginal Prolapse 48 Repair, Suture Repair Versus Mesh Augmentation: A 49 Urogenecology Perspective." 40 Q. Do you also discuss how patients can 41 dysparemia will require a surgical intervention? 41 dysparemia will require a surgical intervention? 42 dysparemia will require a surgical intervention? 43 MR. SLATER: Objection. 44 Q. Mand at the testimony plaintiffs' counsel 45 Expected to the vaginal canal, was it your testimony plaintiffs' counsel 46 Gype					
10 wanted to seek input from someone such as yourself, a 11 precept or a proctor, were they available to do such? 12 A. Absolutely. 13 Q. Plaintiffs' counsel asked you some questions 14 about the IFU and the specific — in certain specific 15 sections of the IFU. 16 Do you recall that? 17 A. Yes. 18 Q. Look at the very front of the IFU. It 19 date, straining on the use of Gynecare Prolifi® 20 Pelvic Floor Repair Systems is recommended and 21 available. 22 Po you see that? 23 A. How far down are we? 24 Q. On the very first page, the third line. 25 A. Yes. 26 Q. And it also referenced the recommended 27 surgical technique guide right below that? 28 A. Yes. 29 Page 531 20 Q. And it also referenced for surgeons like 29 Q. The intended for surgeons like 30 Q. The intended for surgeons like 40 Q. Is the IFU littended for surgeons like 51 yourself? 52 A. Yes. 53 A. Yes. 54 Q. It think so, yes. 55 A. Yes. 55 A. Yes. 56 A. I think so, yes. 67 Q. Turn to Exhibit Number 5, "Vaginal Prolapse 68 Repair, Suture Repair Versus Mesh Augmentation: A 69 Urogynecology Perspective." 61 A. I think so, yes. 62 Q. It was the raise antient becoming 63 the rainey and the end of surgeons like 64 Under what are the risks, of crossion, and 65 and the surgical intervention? 65 are evaluable. 65 yourself? 66 A. I think so, yes. 67 Q. Turn to Exhibit Number 5, "Vaginal Prolapse 68 Repair, Suture Repair Versus Mesh Augmentation: A 69 Urogynecology Perspective." 60 A. I have it here. 61 Q. It is the article from 2012. 61 The WITNESS: Yes. 61 MR. SIATER: Objection. 61 THE WITNESS: Yes. 62 D. Ob you also discuss how patients can 63 significantly improve with different therapies? 64 Q. Do you also discuss how patients can 65 James for the surgical intervention? 76 James for the surgical intervention? 77 THE WITNESS: Yes. 78 James for the surgical intervention? 79 Q. Turn to the found that Ahed study that looked at risk of crossing, and unconstant the different therapies? 79 Q. Do you also discuss how patients can 79 Q. Turn to page 330 and 331. You					
11 Precept or a proctor, were they available to do such? 12 A. Absolutely. 13 de a systematically looked at risk of crossion, and 14 about the IFU and the specific — in certain specific 15 sections of the IFU. 15 mesh ultrasound study by Velemir. You know what, 16 Do you recall that? 17 A. Yes. 18 Q. Look at the very front of the IFU. It 18 states, training on the use of Gynecure Prolific® 19 object in the front of the IFU. It 20 Pelvic Floor Repair Systems is recommended and 21 available. 22 Do you see that? 23 A. How far down are we? 24 Q. On the very first page, the third line. 25 A. Yes. 26 Q. Plaintiff's counsel asked you some questions 27 Page 531 28 Q. Indies and the specific — in certain specific 29 Page 532 20 A. How far down are we? 21 A. Yes. 22 Q. Was the transvaginal mesh procedure also 23 developed by surgeons? 24 Q. On the very first page, the third line. 25 A. Yes. 26 Q. Plaintiff's counsel asked you some questions. 27 Page 531 28 Page 531 39 A. Yes. 30 A. Yes. 30 A. Yes. 31 about the patient brochure, the initial patient patient brochure, the initial patient patient patient patient patient patient patient patient procedure also patients in patient		·			
12 A. Absolutely. 13 Q. Plaintiffs' counsel asked you some questions 13 the range was from zero and up. 14 Q. Turn to Exhibit Number 7, the transvaginal 15 sections of the IFU. 16 Do you recall that? 16 In Do you recall that? 17 A. Yes. 18 Q. Look at the very front of the IFU. It 19 states, training on the use of Gynecare Prolift® 20 Pelvic Floor Repair Systems is recommended and 21 available. 22 Do you see that? 23 A. How far down are we? 24 Q. On the very first page, the third line. 25 A. Yes. 26 Q. Nath it also referenced the recommended 27 Q. On the very first page, the third line. 28 surgical technique guide right below that? 29 Look at the IFU intended for surgeons like 30 A. Yes. 31 A. Yes. 42 Q. Is the IFU intended for surgeons like 43 A. I think so, yes. 44 Q. Is the IFU intended for surgeons like 54 Q. I state IFU intended for surgeons like 55 yourself? 56 A. I think so, yes. 57 Q. Turn to Exhibit Number 5, "Vaginal Prolapse 58 Repair, Suture Repair Versus Mesh Augmentation: A 59 Urogynecology Perspective. 50 A. These of the recommended 51 A. Share in the surgical intervention? 52 A. Share in the surgical intervention? 53 A. Yes. 54 Q. It's the article from 2012. 55 D. If the WITNESS: Yes. 56 D. MR. SLATER: Objection. 56 MR. SLATER: Objection. 57 THE WITNESS: Yes. 58 MR SNELL: 59 Out also discuss how patients can significantly improve with different therapies? 59 MR, SNELL: 50 MR, SLATER: Objection. 50 C. Hard with affect the the different therapies? 51 Do you recall that about the different 2012. 51 Do you recall that about the different 2012. 52 Deptically proteed with different therapies? 53 Deptically proteed with different therapies? 54 Deptically proteed with different therapies? 55 Deptically proteed with different therapies? 56 Deptically proteed with different therapies? 57 Deptically proteed with different therapies? 58 Paymer and a risk of the mesh material becoming a suggificantly improve with different therapies? 59 Deptically prove with different therapies? 50 MR, SLATER: Objection. 51 D	l				
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	Confidential - Subject to Scipula			
	Page 534			Page 536
1	A. Only a complete physical examination and	1	THE WITNESS: Yes, there is.	
2	consultation with your physician can determine which	2		
3	procedure is right for you.	3	Q. Is there a particular study that you	
4	Q. And the last page of the patient brochure,	4	reference?	
5	does it also include adverse reactions including	5	A. The Halaska study from 2012.	
	infection potentiation, inflammation, adhesion,	6	MR. SNELL: Thank you.	
	fistula, erosion, extrusion, scarring, implant	7	MR. SLATER: I'm going to come back	
8	contraction?	8	around the table and continue questioning you now.	
9	MR. SLATER: Objection. You can	9	Give me one second. Off the video for a second.	
10	answer.	10	THE VIDEOGRAPHER: Going off the	
11	THE WITNESS: Yes, it does.	11	record. The time is 10:57 p.m.	
12	BY MR. SNELL:	12	(Brief recess.)	
13	Q. Turn to Exhibit 760, the "Complications from	13	THE VIDEOGRAPHER: We're back on the	
	vaginally placed mesh in pelvic reconstructive	14	record. The time is 10:59 p.m.	
	surgery."	15	BY MR. SLATER:	
16	A. What exhibit number?	16	Q. Okay. Doctor, you were asked a question a	
17	Q. 760, the 2009 article.	17	few moments ago about the article published by Fatton	
18	A. I have it.	18	and a group of doctors from the TVM group in 2007,	
19	Q. Turn back to Page 530. You were asked about	19	which was actually published online in 2006.	
20	the complications and whether with Prolift® there	20	Do you remember that question?	
21	could be life-changing complications.	21	A. Yes.	
22	Do you recall that?	22	Q. Are you familiar with that study?	
23	A. Yes.	23	A. I'd have to review it again to give you	
24	Q. Can there be life-changing complications	24	. 1	
25	with any pelvic organ prolapse surgery?	25	Q. Do you know anything about that study, other	
	Page 535			Page 537
				_
1	A. Yes.	1	than the fact that it was some TVM doctors reporting	
1 2		1 2	than the fact that it was some TVM doctors reporting on the results of patients with the Prolift®? Is	Ü
	A. Yes.			Ü
2	A. Yes.Q. And that would include pelvic pain or	2	on the results of patients with the Prolift®? Is	Ü
2 3	A. Yes. Q. And that would include pelvic pain or dyspareunia?	2 3	on the results of patients with the Prolift®? Is there anything you can tell me about it, as you sit	Ü
2 3 4 5	A. Yes. Q. And that would include pelvic pain or dyspareunia? A. It would.	2 3 4	on the results of patients with the Prolift®? Is there anything you can tell me about it, as you sit here right now?	Ü
2 3 4 5	 A. Yes. Q. And that would include pelvic pain or dyspareunia? A. It would. Q. Turn, if you would, to the FDA 2011 alert, 	2 3 4 5	on the results of patients with the Prolift®? Is there anything you can tell me about it, as you sit here right now? A. That it was a study of Prolift®.	Ü
2 3 4 5 6	 A. Yes. Q. And that would include pelvic pain or dyspareunia? A. It would. Q. Turn, if you would, to the FDA 2011 alert, Exhibit 451. 	2 3 4 5 6	on the results of patients with the Prolift®? Is there anything you can tell me about it, as you sit here right now? A. That it was a study of Prolift®. Q. Anything beyond that?	Ü
2 3 4 5 6 7	 A. Yes. Q. And that would include pelvic pain or dyspareunia? A. It would. Q. Turn, if you would, to the FDA 2011 alert, Exhibit 451. A. I have it. 	2 3 4 5 6 7	on the results of patients with the Prolift®? Is there anything you can tell me about it, as you sit here right now? A. That it was a study of Prolift®. Q. Anything beyond that? A. That it had results regarding Prolift®.	
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Page 538 Page 540 1 first available to Ethicon, Ethicon needed to be Q. Well, let me ask you this: With regard to 2 concerned that the TVM group, some of the preeminent 2 that study, did you list it for any particular reason, 3 physicians with regard to the TVM procedure/the 3 or was it just part of a laundry list of studies that Prolift® procedure were getting 17% shrinkage, right? 4 you referred to just so that you could be sure that 5 MR. SNELL: Objection, form. you had referred to these articles in case you wanted THE WITNESS: I missed the beginning to talk about them at trial? 6 part of that question after the rest of it. A. No, it certainly involved me forming my BY MR. SLATER: opinion. Q. When Ethicon saw the data that's reported Q. What about that article was significant to 10 that Fatton article -you in forming your opinion, the Fatton 2006 article 11 A. Yes. 11 about the 110 patients? 12 Q. -- you would agree that Ethicon needed to be 12 A. That it was a published study on Prolift®. 13 concerned that the TVM group doctors, among the most Q. What about the study was significant to you 13 proficient in the world at doing the Prolift®, were 14 in forming your opinions? getting 17% shrinkage? 15 A. That it reported on Prolift®, the outcomes. 16 A. No. 16 Q. The fact that outcomes were reported in that Q. Meaning 17% of the patients were being article, that was the significant fact with regard to 17 reported with shrinkage. that study that you relied on? 18 19 MR. SNELL: Objection, form. Go ahead. 19 A. That's one of them. THE WITNESS: No. O. What else? 20 20 BY MR. SLATER: 21 21 A. That's the main thing that I report on. Q. You as an expert for Ethicon, do you think Outcomes is the whole topic that we're talking about. 22 22 23 23 there's anything of concern about the fact that in Q. Was there anything about -- rephrase. 24 that study it was documented that 17% of those 24 Are you saying that because there was an patients with Prolifts® were found to have shrinkage article that reported on outcomes, regardless of what Page 539 Page 541 1 of the mesh? 1 those were, that's significant to you? 2 Any adverse outcome is concerning. A. Ask the question again. Q. What should Ethicon have done in response to Q. Are you saying that the fact that the Fatton 3 4 article reports outcomes of the Prolift® procedure in 4 that data, anything? I don't know. and of itself, the fact that there was a report of Q. Do you know what the conclusion was of the outcomes, that that was what was significant to you? 7 Fatton article authors in that article that was 8 published online at the end of 2006? Q. Was there anything about the particular A. Are you asking me to recall a specific 9 outcomes that were reported that were of significance 9 10 conclusion from that paper. 10 to you? 11 Q. Do you remember? Do you know? A. If you'd like to get out the article, I can 11 12 I do not recall. 12 look it through, and I can't recall right now. 13 Q. Is it referenced in your report? 13 Q. Is there anything that you referred in your report to saying in that article, these outcomes were 15 Q. The conclusion by the authors? referenced and this is significant to me? 16 A. The report, the article is referenced in my 16 A. I believe that it was one of the first articles that actually reported on the actual Prolift® 17 report. 17 Q. Well, as you sit here now, do you know what procedure, so that's significant. 18 19 the conclusion was by the authors? 19 Q. Here's my question: Was there anything A. I listed many, many studies. They all have about what was reported in that article that you 20 21 many conclusions. How could you expect me to remember referenced in your report as having been of 22 all the conclusions? significance to you, any specific finding in that 22 23 Q. Well, I remember them so... article, anything that was reported in that article? 24 A. You're asking the questions, it's easy that Did you talk about anything like that in your report? 25 way. 25 A. (Witness reviews document.) I'm having

		e 542	Page 54
1			, 8
2	•		A. Because it's always great to have lots of
3	along. O. I don't know.		data.
4	· ·	4	
5	MR. SNELL: Page 21. I only pointed		5 Prolift®, they need to take seriously if there is a
6	him to it because he couldn't remember whether it was		5 need for long-term data before doctors can say, yes,
7	TVM or Prolift®.		1
8	MR. SLATER: It's okay.	8	
9	BY MR. SLATER:	9	<u> </u>
LO	Q. It's on Page 21, end of at the top of the	10	
L1	first full paragraph, a third of the way down the	11	1 2. 3
L2	page.	12	•
13	A. Yes, I specifically reference it because	13	
L4	it's the first study of the Prolift® system to be	14	
L5	published in peer-reviewed journals.	15	
L6	Q. So other than the fact that this was the	16	
L7	first study published with regard to the Prolift®, was	17	1
18	there anything else that was of significance to you	18	
L9	within the content of the article, any of the data	19	
20	that was reported?	20	•
21	A. I would have to get out the article and look	22	
22		22	
23	Q. You did not in your report discuss any of	23	
24	•	24	· ·
25	A. I do not reference it specifically to that	25	THE WITNESS: I think they did.
	Pag	e 543	Page 54
1	report, correct.	1	MR. SLATER: Move to strike from and.
2	Q. In fact, nowhere in your report do you point	2	BY MR. SLATER:
3	out that the Fatton article reports a 17% shrinkage	3	Q. And if Ethicon needed to have long-term data
4	rate with the Prolift®, that's not mentioned in your	4	to prove the safety and effectiveness of the Prolift®,
5	report anywhere, right?	į	according to the people who created the procedure, and
6	A. That's correct.	6	5 they're saying that at the end of 2006, it was
7	Q. And what you don't mention also is the	-	
ρ	Q. And what you don't mention also is the	1 '	7 probably premature to put the Prolift® on the market
8			probably premature to put the Prolift® on the market in March of 2005; isn't that so?
9	•		3 in March of 2005; isn't that so?
9	conclusion by the authors, which is that long-term	8	3 in March of 2005; isn't that so? MR. SNELL: Objection, form.
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	Confidencial - Subject to Scipul			D ~
	Page 546			Page 548
1	Q. It's Exhibit 895.		correct?	
2	A. I have it here.	2	And the witness, Dr. Lucente says, yes,	
3	Q. And that article, which you're one of the	3	right?	
4	co-authors on, 1.7% of the patients in that study had	4	A. Correct.	
5	persistent dyspareunia at six months, correct?	5	Q. So Dr. Lucente testified under oath that by	
6	A. I don't see it here, but I agree that	6	2005 to early 2006, he had had discussions with people	
7	that's, I think, one of the conclusions.	7		
8	Q. Which means that those patients, whatever	8	from his perspective, chronic pain syndromes, if	
9	treatment they got, the dyspareunia was refractory to	9	someone had a systemic chronic pain syndrome, they	
10	that treatment and the patients continued to have that	10	would be at a heightened risk for developing chronic	
11	complaint, correct?	11	pain after the insertion of the Prolift®; that's what	
12	A. At that time point.	12	he testified to, correct?	
13	Q. Right.	13	MR. SNELL: Object to the form. He	
14	A. Yes.	14	testified on that subject to different dates, multiple	
15	Q. At the six months?	15	different dates.	
16	A. Yes.	16	MR. SLATER: Do you want to testify?	
17	Q. Okay. What ended up happening with those	17	You want to switch seats because it's too late for	
18	patients?	18	this now.	
19	A. I don't know.	19	BY MR. SLATER:	
20	(Document marked for identification	20	Q. Am I correct?	
21	as Murphy Deposition Exhibit No. 8.)	21	MR. SLATER: So move to strike the	
22	BY MR. SLATER:	22	comment by counsel.	
23	Q. I'm going to mark as Exhibit Murphy-8 the	23	THE WITNESS: You read the testimony	
24	November 2, 2012 deposition transcript of Dr. Lucente	24	MR. SNELL: Objection, form. Go ahead.	
25	and ask you to turn to Page 104.	25	MR. SLATER: I'll ask a new question.	
	Page 547			Page 5/10
	Page 547		DVIAD GV (TED	Page 549
1	A. Okay.	-	BY MR. SLATER:	Tage 547
2	A. Okay.Q. On Page 104 Dr. Lucente is asked a question	2	Q. Did you do you dispute what Dr. Lucente	Tage 347
	A. Okay.Q. On Page 104 Dr. Lucente is asked a question on Line 6	2	Q. Did you do you dispute what Dr. Lucente testified to here on Page 104?	Tage 349
2 3 4	A. Okay. Q. On Page 104 Dr. Lucente is asked a question on Line 6 MR. SNELL: Let me get there.	2 3 4	Q. Did you do you dispute what Dr. Lucente testified to here on Page 104? A. Yes.	Tage 349
2 3 4 5	A. Okay. Q. On Page 104 Dr. Lucente is asked a question on Line 6 MR. SNELL: Let me get there. BY MR. SLATER:	2 3 4 5	Q. Did you do you dispute what Dr. Lucente testified to here on Page 104?A. Yes.Q. Do you dispute that he provided that	Tage 349
2 3 4	A. Okay. Q. On Page 104 Dr. Lucente is asked a question on Line 6 MR. SNELL: Let me get there. BY MR. SLATER: Q. And you knew at least by 2005 to early 2006	2 3 4 5	 Q. Did you do you dispute what Dr. Lucente testified to here on Page 104? A. Yes. Q. Do you dispute that he provided that information to Ethicon in 2005 to early 2006? 	Tage 347
2 3 4 5	A. Okay. Q. On Page 104 Dr. Lucente is asked a question on Line 6 MR. SNELL: Let me get there. BY MR. SLATER: Q. And you knew at least by 2005 to early 2006 that those individuals who had migraines and	2 3 4 5 6	 Q. Did you do you dispute what Dr. Lucente testified to here on Page 104? A. Yes. Q. Do you dispute that he provided that information to Ethicon in 2005 to early 2006? A. Yes. 	Tage 347
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2 3 4 5 6 7	A. Okay. Q. On Page 104 Dr. Lucente is asked a question on Line 6 MR. SNELL: Let me get there. BY MR. SLATER: Q. And you knew at least by 2005 to early 2006 that those individuals who had migraines and interstitial cystitis and other similar chronic systemic I'm sorry systemic chronic pain	2 3 4 5 6	 Q. Did you do you dispute what Dr. Lucente testified to here on Page 104? A. Yes. Q. Do you dispute that he provided that information to Ethicon in 2005 to early 2006? A. Yes. Q. Do you dispute that Ethicon was aware of that information at that time? 	Tage 347
2 3 4 5 6 7 8	A. Okay. Q. On Page 104 Dr. Lucente is asked a question on Line 6 MR. SNELL: Let me get there. BY MR. SLATER: Q. And you knew at least by 2005 to early 2006 that those individuals who had migraines and interstitial cystitis and other similar chronic systemic I'm sorry systemic chronic pain syndromes would be at a heightened risk for developing	2 3 4 5 6 7 8	Q. Did you do you dispute what Dr. Lucente testified to here on Page 104? A. Yes. Q. Do you dispute that he provided that information to Ethicon in 2005 to early 2006? A. Yes. Q. Do you dispute that Ethicon was aware of that information at that time? A. At that time period, yes.	Tage 347
2 3 4 5 6 7 8	A. Okay. Q. On Page 104 Dr. Lucente is asked a question on Line 6 MR. SNELL: Let me get there. BY MR. SLATER: Q. And you knew at least by 2005 to early 2006 that those individuals who had migraines and interstitial cystitis and other similar chronic systemic I'm sorry systemic chronic pain	2 3 4 5 6 7 8	 Q. Did you do you dispute what Dr. Lucente testified to here on Page 104? A. Yes. Q. Do you dispute that he provided that information to Ethicon in 2005 to early 2006? A. Yes. Q. Do you dispute that Ethicon was aware of that information at that time? A. At that time period, yes. Q. Do you dispute that Dr. Lucente had drawn 	Tage 347
2 3 4 5 6 7 8 9	A. Okay. Q. On Page 104 Dr. Lucente is asked a question on Line 6 MR. SNELL: Let me get there. BY MR. SLATER: Q. And you knew at least by 2005 to early 2006 that those individuals who had migraines and interstitial cystitis and other similar chronic systemic I'm sorry systemic chronic pain syndromes would be at a heightened risk for developing	2 3 4 5 6 7 8 9	Q. Did you do you dispute what Dr. Lucente testified to here on Page 104? A. Yes. Q. Do you dispute that he provided that information to Ethicon in 2005 to early 2006? A. Yes. Q. Do you dispute that Ethicon was aware of that information at that time? A. At that time period, yes. Q. Do you dispute that Dr. Lucente had drawn that conclusion by 2005 to early 2006?	Tage 347
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1	confidencial bablece to belpar		
	Page 550		Page 552
	what to say, yes or no.		following Prolift® insertion?
2	MR. SLATER: Could you read it back to	2	A. I disagree with the premise of your
3	him, please.	3	statement.
4	(The court reporter read back the	4	Q. You don't even know what I'm going to ask
5	record as requested.)	5	you.
6	MR. SNELL: Note my objection again.	6	A. I know, because I'm not stating an answer to
7	THE WITNESS: I think I already	7	your question. I'm disagreeing with that premise.
8	testified to this. I think that that's opinion of one	8	Q. Okay. What do you say to a patient who had
9	doctor. I think the time frame, I think he's probably	9	a systemic chronic pain condition, had a Prolift® put
10	not recalling that correctly, but apart from that,	10	in her body and developed severe pain afterwards and
11	that's the opinion of one doctor to some people in	11	the doctor didn't know that that woman was at a
12	Ethicon.	12	heightened risk, according to what I just read to you
13	BY MR. SLATER:	13	from Dr. Lucente's deposition, and the doctor himself
14	Q. My question is this I'll ask a new	14	says, if I knew that, I wouldn't have used the
15	question.	15	Prolift® with her? If I knew that that was a concern,
16	MR. SLATER: Do you have a problem?	16	I wouldn't have used the Prolift® with this woman.
17	Are you rolling your eyes at me now?	17	What do you say to that woman about Ethicon's failure
18	MR. SNELL: No, I just I think we've	18	to get that information out to her?
19	covered this before a couple times.	19	MR. SNELL: Objection.
20	MR. SLATER: You opened the door and	20	BY MR. SLATER:
21	started talking about this when you asked him about	21	Q. To her doctor?
22	the webinar, so I'm going to cover the issue now.	22	MR. SNELL: Objection, form.
23	MR. SNELL: No. You marked the webinar	23	THE WITNESS: I would say that it's my
24	as an exhibit. I just asked him a question about a	24	opinion no matter what surgery she had, she was at a
25	sentence right next to the sentence you asked him	25	heightened risk for that outcome.
	Page 551		Page 555
1	about that you want that you moved to strike.	1	BY MR. SLATER:
2	MR. SLATER: You talked about it, I'm	2	Q. And if she said, well, you know, I would
3	going to go through it. I told you if you question		
1 -		3	have liked to know that I could have had something
4	him, I'm going to question him thoroughly.	3 4	have liked to know that I could have had something other than the Prolift® because rephrase.
	him, I'm going to question him thoroughly. MR. SNELL: All I did was		_
4		4	other than the Prolift® because rephrase. And if she said to you, you know what, I
4 5	MR. SNELL: All I did was	4 5	other than the Prolift® because rephrase. And if she said to you, you know what, I
4 5 6	MR. SNELL: All I did was MR. SLATER: What are we doing?	4 5 6	other than the Prolift® because rephrase. And if she said to you, you know what, I would have liked to have known that I had a higher
4 5 6 7	MR. SNELL: All I did was MR. SLATER: What are we doing? MR. SNELL: ask him about what you	4 5 6	other than the Prolift® because rephrase. And if she said to you, you know what, I would have liked to have known that I had a higher risk with the Prolift® and I could have decided not to
4 5 6 7 8	MR. SNELL: All I did was MR. SLATER: What are we doing? MR. SNELL: ask him about what you moved to strike.	4 5 6 7 8	other than the Prolift® because rephrase. And if she said to you, you know what, I would have liked to have known that I had a higher risk with the Prolift® and I could have decided not to use it if I wanted to, would that information
4 5 6 7 8	MR. SNELL: All I did was MR. SLATER: What are we doing? MR. SNELL: ask him about what you moved to strike. MR. SLATER: You can ask him whatever you want, but don't roll your eyes at me for following	4 5 6 7 8	other than the Prolift® because rephrase. And if she said to you, you know what, I would have liked to have known that I had a higher risk with the Prolift® and I could have decided not to use it if I wanted to, would that information A. Again, you're using the term higher, that
4 5 6 7 8 9	MR. SNELL: All I did was MR. SLATER: What are we doing? MR. SNELL: ask him about what you moved to strike. MR. SLATER: You can ask him whatever you want, but don't roll your eyes at me for following	4 5 6 7 8 9	other than the Prolift® because rephrase. And if she said to you, you know what, I would have liked to have known that I had a higher risk with the Prolift® and I could have decided not to use it if I wanted to, would that information A. Again, you're using the term higher, that implies a comparison. There is no comparative data in
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			lon and Order of Confidentiality	
		e 554		age 556
1	A. Your question asked about all sorts of		A. Correct.	
2	things.		Q. What about how to address dyspareunia and	
3	Q. I'm asking you a clean question because I		3 pain, same answer?	
4	didn't ask you about the time period.		A. Correct.	
5	A. Okay.		Q. Do you know whether those slide decks were	
6	Q. It's late, I understand it can be confusing,		seen by all surgeons using the Prolift®?	
7	so here is a very simple question: Do you disagree		7 A. I do not.	
8	with Dr. Lucente to the extent that he offers the		Q. Do you know which preceptors or physicians	
9	opinion that a patient with a systemic chronic pain		who conducted professional education used those slide	
10	syndrome has a higher risk to develop chronic pain	1	decks as opposed to any other materials?	
11	after Prolift® surgery?	1	A. I think anyone who had those slide decks	
12	MR. SNELL: Objection, form.	1	used them, any of the preceptors that acted on behalf	
13	THE WITNESS: You're saying that he	1	3 of Gynecare.	
14	says that's a higher risk. I don't know what that	1	Q. Why do you believe that they were used?	
15	means, a higher risk than someone who doesn't have	1	A. Because when people give professional	
16	chronic pain?	1	6 education talks on behalf of a company, they usually	
17	BY MR. SLATER:	1	7 use slide decks from that company.	
18	Q. Right.	1	Q. Did you ever use the professional education	
19	A. I don't disagree with that.	1	slide decks in a professional education event you were	
20	Q. You agree with him on that?	2) involved in?	
21	A. I don't disagree that a patient who has a	2	A. I think so.	
22	Prolift® who has a pre-existing condition of chronic	2	Q. What do you mean you think so; either you	
23	pain is not at a higher risk of having that outcome	2	3 did or you didn't?	
24	after the Prolift® than someone who does not have a	2	A. I can't recall exactly.	
25	pre-existing pain syndrome, okay, because I think	2	Q. Do you know which one well, let me ask	
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		e 555		age 557
	that's the case in any surgery that someone has, and		you this: You can't recall whether you used a slide	age 557
2	that's the case in any surgery that someone has, and I've said this about 15 times tonight.		you this: You can't recall whether you used a slide deck, so you wouldn't be able to tell me which you	age 557
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		страта			
		Page 558			Page 560
1	Q. So to the extent that the information in the		1	CERTIFICATION	
2	IFU about adverse events, contraindications or		2	I, MARGARET M. REIHL, a Registered	
3	warnings, that type of information, to the extent		3	Professional Reporter, Certified Realtime Reporter,	
4	that's found in the IFU, you wouldn't expect a patient		4	Certified Shorthand Reporter, Certified LiveNote	
5	to read that, understand it, utilize it, because it's		5	Reporter and Notary Public, do hereby certify that the	
6	not intended for patients, correct?		6	foregoing is a true and accurate transcript of the	
7	MR. SNELL: Objection, form. Go ahead.		7	testimony as taken stenographically by and before me	
8	THE WITNESS: Correct.		8	at the time, place, and on the date hereinbefore set	
9	BY MR. SLATER:		9	forth.	
10	Q. The TVM study rephrase.		10	I DO FURTHER CERTIFY that I am neither	
11	The TVM procedure was developed by some		11	a relative nor employee nor attorney nor counsel of	
12	French surgeons, correct?		12	any of the parties to this action, and that I am	
13	A. That's what I believe, yes.		13	neither a relative nor employee of such attorney or	
14	Q. With the involvement of Axel Arnaud of		14	counsel, and that I am not financially interested in	
15	Gynecare France from the very beginning, correct?		15	the action.	
16	A. I do not know.		16		
17	Q. Do you know whether Gynecare ran the		17		
18	logistics for that TVM procedure to be developed?		18	Margaret M. Reihl, RPR, CRR, CLR	
19	A. I think it ran the study. I don't know if		19	CSR #XI01497 Notary Public	
20	it ran the logistics for the initiation of it as a		20	Col #Mi01491 Hotaly Futile	
21	concept.		21		
22	Q. You don't know what involvement somebody		22		
23	from Gynecare or Ethicon had with the TVM doctors in		23		
24	developing the TVM procedure, correct?		24		
25	A. Correct.		25		
		Page 559			Page 561
1			1	INSTRUCTIONS TO WITNESS	
1	MR. SLATER: No other questions.				
1 2	MR. SLATER: No other questions. MR. SNELL: That's all I have. I don't		2		
	MR. SNELL: That's all I have. I don't have anything.			Please read your deposition over carefully	
2	MR. SNELL: That's all I have. I don't have anything. MR. SLATER: Did you strike anything?		2	and make any necessary corrections. You should	
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		Page 562			Page 564
1	ERRATA SHEET		1	LAWYER'S NOTES	
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1					
2	ACKNOWLEDGMENT OF DEPONENT				
3					
4	I, MILES MURPHY, M.D., do				
5	hereby certify that I have read the foregoing pages, 1-564, and that the same is a correct transcription				
1	of the answers given by me to the questions therein				
8	propounded, except for the corrections or changes in				
9	form or substance, if any, noted in the attached				
10	Errata Sheet.				
11					
12					
12					
13	MILES MURPHY, M.D. DATE				
14	,				
15					
16					
17					
10	Subscribed and sworn				
18	to before me this day of, 2012.				
19					
	My commission expires:				
20					
21					
	Notary Public				
22					
23 24					
25					
1					